



Central arteriovenous anastomosis for the treatment of patients with uncontrolled hypertension and paroxysmal AF

William Eysenck, MBChB,^a Jet van Zalen, MSc,^a Nick Freemantle, PhD,^b Guy Lloyd, MD,^c Steve Furniss, MBBS,^a and Neil Sulke, MD^a *Eastbourne, London, United Kingdom*

A central iliac arteriovenous anastomosis, the 'coupler' (ROX Medical, California, USA) results in a significant reduction in blood pressure in hypertensive patients. This study assessed the change in AF burden following coupler implantation in patients with paroxysmal AF (PAF) and hypertension. Good blood pressure control using the coupler results in a significant reduction in AF burden. (*Am Heart J* 2019;207:86-87.)

Hypertension (HTN) and atrial fibrillation (AF) are strongly associated. The relationship of AF to severity or control of HTN is less clear.¹ Controlled HTN does not affect AF ablation outcome but uncontrolled HTN causes higher AF recurrence.¹

A central iliac arteriovenous anastomosis, called a 'coupler' (ROX Medical, California, USA) is commercially available in Europe under CE mark and alters mechanical properties and reduces blood pressure (BP) in patients with resistant and/or uncontrolled HTN.² Incorporating a segment of vein into the central arterial circuit reduces BP by improving arterial compliance and lowering vascular resistance, effects which could modify AF burden. Arrhythmia outcomes were assessed using beat-to-beat monitoring using Medtronic Reveal XT implantable cardiac monitors (ICMs) (Minnesota, USA).

Methods

This was a prospective study of patients with PAF eligible for the ROX Control HTN-03 trial, a multicenter registry assessing impact of the coupler on BP.³ Written informed consent was obtained from all participants. Patients underwent implantation of an ICM, were moni-

tored for 1 month prior to the coupler and were followed for 6 months. Patients underwent device downloads at baseline, and at monthly intervals for 6 months. AF burden was calculated as the percentage of time the patient was in AF episodes of 30 seconds or longer. The study was performed at Eastbourne General Hospital, UK. No extramural funding was used to support this work.

Study population

Seventeen patients were screened. Seven patients were excluded: 4 elected not to proceed and 3 did not have resistant HTN following 24-hour BP monitoring. Patients were 48–81 years, mean 67.0 ± 8.3 (7 males) and were taking a median of 3 anti-hypertensives with a mean of 1 drug intolerance. All were taking diuretics (8 loop diuretics and 2 thiazide diuretics). All patients had a diagnosis of PAF (diagnosed for a mean of 26.5 months) made on the basis of Holter monitors.

The ROX coupler

A 4F sheath was inserted into the right femoral artery. A 13F venous introducer was inserted into the femoral vein. A crossing needle punctured from the iliac vein into the iliac artery. The coupler was deployed and a 4 mm diameter balloon was used to create an arteriovenous fistula.

Statistics analysis

ICM downloads were performed monthly affording beat-to-beat arrhythmia monitoring allowing repeated AF measures over 6 months (7 measures per subject) in 10 subjects. A generalized mixed model with random intercept term was performed. Degrees of freedom were derived from the number of patients. Time was incorporated as a fixed term as a proportion of 6 months. The model was fitted with $\log_e(1 + AF)$ as the response

From the ^aEastbourne General Hospital, Eastbourne, United Kingdom, ^bUniversity College London, London, United Kingdom, and ^cHeart Valve Clinic & Echocardiography Laboratory, Barts Heart Centre, St. Bartholomew's Hospital, London, United Kingdom / William Harvey Research Institute, QMUL, London, United Kingdom/Institute of Cardiovascular Sciences, UCL, London, United Kingdom.

Submitted July 7, 2018; accepted September 24, 2018.

Reprint requests: William Eysenck, MBChB, Eastbourne General Hospital, Eastbourne, BN21 2UD United Kingdom.

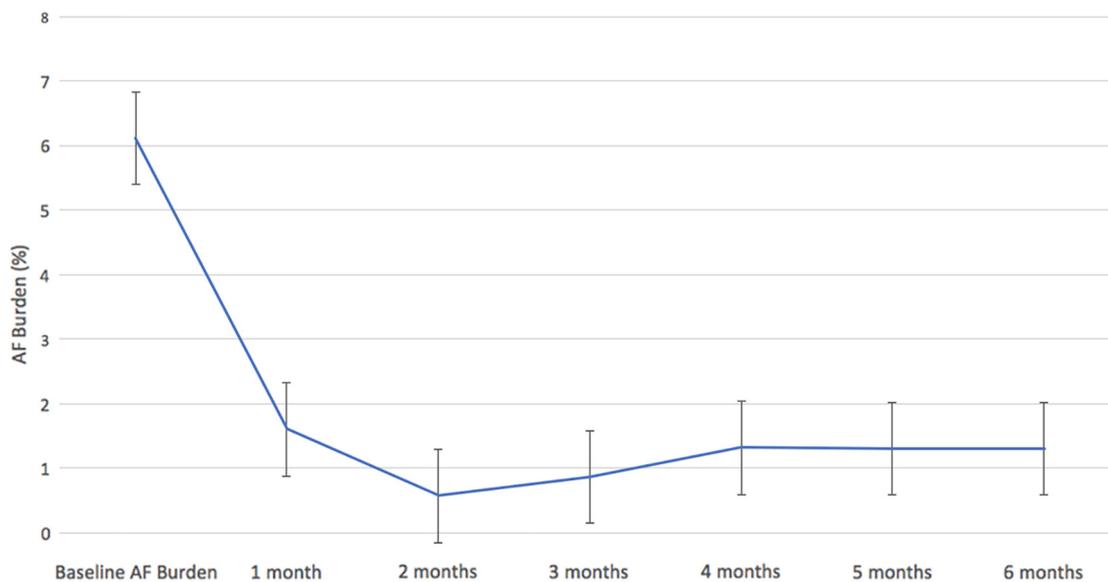
E-mail: william.eysenck@nhs.net

0002-8703

Crown Copyright © 2018 Published by Elsevier Inc. All rights reserved.

<https://doi.org/10.1016/j.ahj.2018.09.010>

Figure



Change in AF burden over time. Error bars represent standard error of mean.

variable giving 'relative' change in AF burden. $P < .05$ was considered significant.

Results

Detailed demographic data is included in a separate publication.⁴ One month pre-coupler implantation ICM monitoring demonstrated 7/10 patients had sustained AF (greater than 30 seconds). At 6 months 1 patient had sustained AF. Change in AF burden for all 10 patients is shown in Figure. Mean AF burden at baseline was 6.1% and at 6 month follow-up 1.3%.

The analysis shows systematic reduction in AF burden with a relative reduction of 0.709 (95% CI 0.532 to 0.945; $P = .024$).

Discussion

A 71% reduction in AF in previously hypertensive patients during 6 months beat-to-beat follow up was observed post-coupler. With no randomized control group it is not possible to assess whether this reduction is attributable to the intervention or due to other patient characteristics or both.

The coupler could benefit patients with AF by reducing BP. The device also reduces systemic vascular resistance, reduces peripheral sympatho-inhibition, increases arterial compliance, tissue oxygen delivery, venous oxygenation and increases pulmonary blood flow. A combination of these mechanisms could explain the reduction in AF burden observed.

Conclusions

This hypothesis-generating observational study suggests good BP control using the coupler in patients with resistant and/or uncontrolled hypertension and PAF induces a significant reduction in AF burden with beat-to-beat monitoring.

Disclosures

The authors have nothing to disclose. The authors are solely responsible for the design and conduct of this study, all study analyses, the drafting and editing of the paper and its final contents.

References

1. Santoro F, Di Biase L, Trivedi C, et al. Impact of uncontrolled hypertension on atrial fibrillation ablation outcome. *JACC Clin Electrophysiol* 2015;1(3):164-73.
2. Lobo MD, Sobotka PA, Stanton A, et al. Central arteriovenous anastomosis for the treatment of patients with uncontrolled hypertension (the ROX CONTROL HTN study): a randomised controlled trial. *Lancet* 2015;385(9978):1634-41.
3. *Registry to evaluate the ROX coupler in patients with resistant of uncontrolled hypertension. ClinicalTrials.gov identifier.* 2015. NCT01885390.
4. Eysenck W, van Zalen J, Freemantle N, et al. The hemodynamic effects of a central iliac arteriovenous anastomosis at 6 months in patients with resistant and uncontrolled hypertension. *Am Heart J* 2018 <https://doi.org/10.1016/j.ahj.2018.09.010>.