Renal Denervation: Back to the Future?

RCP – BHS Hypertension State of the Art
27th June 2016

Adrian J.B. Brady MD, FRCP(Glasg), FRCPE, FBHS, FESC, FAHA
Associate Professor, University of Glasgow
Consultant Cardiologist
Glasgow, UK

President, British Hypertension Society
Council, British Cardiovascular Society
European Society of Cardiology Global Spokesperson for Hypertension

Disclosures:
Research grants from: AstraZeneca, Bayer,
Boehringer Ingelheim, Merck, Roche, Servier
Honoraria/Consultancy: AstraZeneca, Bayer, Boehringer Ingelheim, Merck, Pfizer, Servier
Question: Which risk factor accounts for the most CV disease according to the World Health Organisation?

- 1. Smoking
- 2. Dyslipidaemia
- 3. Family History of CVD
- 4. Obesity
- 5. Diabetes
- 6. Hypertension
- 7. Low birth Weight
- 8. Urban pollution
Which risk factor accounts for the most CV disease according to the World Health Organisation?
<table>
<thead>
<tr>
<th>Year</th>
<th>Blood pressure treatment</th>
</tr>
</thead>
<tbody>
<tr>
<td>2000 BC–</td>
<td>Acupuncture, venesection, leeches, cupping</td>
</tr>
<tr>
<td>1900–</td>
<td>Sodium thiocyanate</td>
</tr>
<tr>
<td>1920–</td>
<td>Surgical sympathectomy</td>
</tr>
<tr>
<td>1930–</td>
<td>Reserpine</td>
</tr>
<tr>
<td>1940–</td>
<td>Intravenous pyrogens, ganglion blocking drugs, sulphanilamide, Kempner diet (low salt)</td>
</tr>
<tr>
<td>1950–</td>
<td>Thiazide-type diuretics (chlorothiazide), aldosterone-receptor antagonist (spironolactone), hydralazine, guanethidine</td>
</tr>
<tr>
<td>1960–</td>
<td>Methyldopa, beta blocker (propranolol), loop diuretics (furosemide)</td>
</tr>
<tr>
<td>1970–</td>
<td>Central alpha&lt;sub&gt;2&lt;/sub&gt;-agonist (clonidine), alpha&lt;sub&gt;1&lt;/sub&gt;-blocker (prazosin), angiotensin-converting enzyme (ACE) inhibitors (captopril), calcium channel blocker (verapamil)</td>
</tr>
<tr>
<td>1980–</td>
<td>Potassium-sparing diuretic (amiloride)</td>
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<tr>
<td>1990–</td>
<td>Angiotensin-receptor blockers (losartan)</td>
</tr>
<tr>
<td>2000–</td>
<td>Direct renin inhibitor (aliskiren), renal sympathetic denervation (Symplicity™)</td>
</tr>
</tbody>
</table>
Percentage of Hypertensive Patients with controlled Blood Pressure
(<140/90 mmHg) in Europe

Czech Republic: 17%
England: 21.5%
Frankreich: 33%
Deutschland: 30%
Griechenland: 33.3%
Ungarn: 27.3%
Italien: 28%
Polen: 12%
Spanien: 35.7%
Schweden: 21%
Türkei: 20.7%

© Prof. Schmieder, FAU
Erlangen
Treatment Resistant Hypertension

2013 Definitions: ESC/ESH AHA BHS

1. BP above goal on a rational $\geq 3$ med regimen with complementary mechanisms of action at optimal doses preferably including a diuretic.

BHS: – A+C+D

2. Controlled Resistant Hypertension. BP controlled to goal on $\geq 4$ BP meds (optimal doses, preferably including a diuretic).

Prognosis in Resistant Hypertension

556 patients with TRH, based on office BP

338 (61%) had confirmation of TRH on 24-hr ABPM.

Mean follow-up 4.8 years

Stratified Approach to Diagnosis and Treatment of Resistant Hypertension

1. ABPM / HBPM
2. Identify contributing lifestyle factors
3. Discontinue / minimize drugs that ↑ BP
4. Investigate for secondary causes of hypertension
5. Maximize and optimize pharmacotherapy
6. Consider interventional procedures
ABPM and HBPM superior to office BP
BP Measurement Artefacts

- Cuff too small = ↑ 10–30 mm Hg
- Talking during measurement:
  ↑ 20 mm Hg

*Clues to measurement artifacts:*
- Less target organ damage than expected
- Hypotensive symptoms with treated

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Suboptimal adherence (concordance)

- Case report: Mrs PC 76  
  HT 15y

- Atenolol 100 mg, Enalapril 20 mg, Amlodipine 10 mg, Doxazosin 8 mg, Bendroflumethiazide 2.5 mg, Amiloride 5 mg.
- Referred for specialist opinion
- 177/79 mm Hg
- Heart sounds normal; heart rate 88, regular
Suboptimal adherence (concordance)

Case report: Mrs PC 76
HT 15y

- Admitted as day case –
given her own medication

- Collapse in hospital shop
- BP 70/40 mm Hg
21 August 2013

Dr Jennifer Foster
Drymen Health Centre
2 Old Gartmore Road
Drymen G63 0DP

Dear Dr Foster

Sxxxxx Axxxxx — DOB 06.05.47
Cxxxxx Road BALFRON G63 xxx

Thank you very much indeed for asking me to examine Mrs Axxxx and it was a pleasure to meet Sxxxx today. Mrs Axxxxx has been treated for high blood pressure for about 20 years, and has been on Bendroflumethiazide 2.5 mg for a long time.

She looks after her health and measures blood pressure at home. This is variable but is often around 150/80 mmHg. This is using an Omron machine, approved by the British Hypertension Society.

You performed ambulatory blood pressure monitoring, averaging 164/94 mmHg without a nocturnal dip, although she did feel rather tense with the device insitu.

Sxxxxx consumes some salt and is on no other medication.

On examination she looked well, blood pressure 165/90 mmHg, gradually falling to 151/89 mmHg.
Effects of salt restriction on blood pressure in ACEi treated patients

Mrs S.A. Clinical Progress

- Only alteration – salt restriction and switch to LoSalt (K+ based)
- HBPM ~ 137/78 mm Hg
Case Presentation:

55 y/o man 12 year HT & arthritis.
HBPM ~156/94 mm Hg. HCTZ 25 + Losartan 100 mg daily. Celebrex 200 mg 1–2 /d

Office BP 162/98 mm Hg & BMI 29

Rx: Switch COX 2 to paracetamol, follow the DASH Eating Plan and take more exercise.
NSAIDs and BP Control (follow up)

1 month follow up visit:
Paracetamol 500 mg bd, HCTZ+ Losartan
Too busy to change eating and exercise patterns.
BP 118/72 mm Hg, BMI unchanged

Re-challenge with celecoxib X 2 raises BP 40 – 50/20 – 25 mmHg within 1–2 days with return to normal BP values within 2–3 days.

Egan BM, unpublished
## Causes of Secondary Hypertension

<table>
<thead>
<tr>
<th>Condition</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>Renal artery stenosis</td>
<td></td>
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<tr>
<td>Sleep apnoea</td>
<td></td>
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<tr>
<td>Drug-induced or drug-related hypertension (e.g. NSAIDs)</td>
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<tr>
<td>Chronic renal disease</td>
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<tr>
<td>Primary aldosteronism</td>
<td></td>
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<tr>
<td>Renovascular disease</td>
<td></td>
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<tr>
<td>Chronic steroid therapy and Cushing’s syndrome</td>
<td></td>
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<tr>
<td>Pheochromocytoma</td>
<td></td>
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<tr>
<td>Coarctation of the aorta</td>
<td></td>
</tr>
<tr>
<td>Thyroid or parathyroid disease</td>
<td></td>
</tr>
</tbody>
</table>

Brady AJB, et al. Mayo Clinic Textbook of Cardiology 2013
Case Report

- 68 year old female
- First diagnosed with hypertension 1979 (age 36)

2007 - 186/86 mm Hg
ramipril/atenolol/valsartan/
amlodipine/furosemide/spironolactone

Renin/aldosterone profile in normal range

MRI adrenals normal

2008 - 187/99 aliskerin added: now on 7 antihypertensive drugs
• 20/09/10- admitted for renal denervation as part of SYMPLICITY-2-HTN trial

• Admission BP 220/120 (same therapy)

• Pre-procedure 190/100
• Post procedure BP 163/77

• No antihypertensives given that night

• Next morning 135/74 pre therapy

• Discharged on atenolol 25mg

• Stopped 1 week later

• 1 year later BP 134/77 mm Hg, no antihypertensive Rx
Creatinine 76, ACR 10.5
Glasgow Renal Artery Sympathectomy Study (GRASS) summary

• Promising treatment for resistant hypertension

• In our hands approx 20-25% ‘non responder’

• The rest- variable degrees of response representing ‘real world experience’

• Considerable need for pre, peri, post procedural care- i.e. not a day case procedure

• Longer term studies in real world and in better defined patient groups required
Stress

Angiotensin II

Chemoreceptors

Baroreceptors

Cardiac afferents

Renal afferents

vagal efferents

Sympathetic efferents

NE

Ach

EPI

Renin

NE

NE

NE
Evidence for Sympathetic Activation in “Essential” Hypertension

Goldstein DS. Hypertension. 1983
Grassi G et al. Hypertension. 1998

* P < 0.05
** P < 0.01
PHYSIOLOGIC EFFECTS OF EXTENSIVE SYMPATHETOMY FOR ESSENTIAL HYPERTENSION: FURTHER OBSERVATIONS

By Edgar V. Allen, M.D., F.A.C.P., and Alfred W. Adson, M.D., Rochester, Minnesota

In previous communications we have presented our experiences with extensive sympathectomy for essential hypertension. We are now reporting our experiences with a large number of patients and with the effects of operation on patients who have been observed over longer periods of time than were those of the earlier reports. We have continued to treat patients with essential hypertension by extensive sympathectomy for we are impressed with the fact that essential hypertension is in many instances an extremely serious disease for which medical treatment is far from satisfactory. Progession of this work, the aim of which was remedy or cure while there yet was possibility of either, opened the opportunity to determine the effects of the operation on blood pressure, symptoms and health, and to learn whether the surgical treatment modified the eventual mortality in essential hypertension. It also became possible to investigate the question of whether good results of operation are transient or permanent and whether or not patients could be selected so that more of them would benefit from operation.

The surgical treatment of essential hypertension is relatively new and the only way one can gain information about the results of extensive sympathectomy is to survey a relatively large number of patients. Such a survey will draw more sharply the distinction between patients who are suitable, and those who are unsuitable for operation.

THE TECHNIC AND RATIONALE OF THE OPERATION

The technic used was that which Adson devised and which has been described in detail elsewhere: it consists of bilateral subdiaphragmatic extraperitoneal resection of the splanchic nerves, celiac ganglia and the upper two lumbar sympathetic ganglia. First the operation is performed on one side and then, about ten days later, on the opposite side. In addition, in the first 25 operations one-third to two-fifths of each suprarenal gland was removed. This procedure apparently did not offer any advantage or disadvantage over removal of only the tumor structures named.

It is known that in essential hypertension the fundamental cause of the

THE HEMODYNAMIC EFFECTS OF SYMPATHECTOMY IN ESSENTIAL HYPERTENSION

By Robert W. Wilkins, M.D., James W. Colburn, M.D., and Meyer H. Halpern, M.D., Boston, Massachusetts

Surgical sympathectomy has been employed so extensively for the treatment of essential hypertension that one might assume its hemodynamic effects to be completely understood. Quite the contrary, however, very little is known concerning its direct vascular or indirect metabolic effects that will explain its success in some cases and its failure in others. Until these matters are fully understood the rationale for surgical treatment, and indeed for medical management, of essential hypertension must remain on an empirical basis. For this reason these problems have been and will continue to be the subject of long-term investigation in this laboratory.

MATERIALS AND METHODS

Patients with essential hypertension selected for splanchicectomy have been made freely available for study through the active cooperation of Dr. Reginald H. Smithwick, under whose direction sympathectomy was performed. They were studied before and again, if possible within three weeks after bilateral operation, usually of the lumbar type. In addition, some patients were studied a third time four to 10 months after operation, whereas a few patients were studied only once—from one to nine years postoperatively.

Arterial pressure was measured with a Hamilton manometer attached to a needle in the brachial or femoral artery. Cardiac output was determined by the Fick principle with the intravenous catheter method of Courmand. Hepatic-portal (splanchnic exclusive of renal and adrenal) blood flow was estimated by the bromsulfalein method of Bradley et al. Both before and after operation the patients, while under study, were given a number of vasomotor stimuli designed to produce, if possible, sympathetic nervous vasoconstriction. The most useful of these stimuli were (a) tilting the subject into the upright position and (b) having him perform theValsalva maneuver.

Cardiac Output. Confirming the observations of others, no great or consistent change was found in basal cardiac output of patients after sympathectomy as compared with before, regardless of how much the arterial

*Presented before the Fifth General Session of the Twenty-ninth Annual Session of the American College of Physicians in San Francisco, California, April 22, 1948.

From the Robert Darrow Evans Memorial, Massachusetts Memorial Hospitals, and the Department of Medicine, Boston University School of Medicine, Boston, Massachusetts.

Ann Intern Med. 1938;11(12):2151-2171

Long Term Effect of Renal Denervation in Human Hypertension

Symptoms

- Onset of hypertension 3 years previously with toxemia of pregnancy, severe headaches, nausea and vomiting, blurred vision, complete incapacity, confined to bed

- Systolic blood pressure: 280, 135, 144, 140, 140, 140, 130, 130, 120
- Diastolic blood pressure: 190, 110, 106, 96, 90, 90, 90, 77
- Maximum concentration: 1.034, 1.029, 1.027, 1.028, 1.026, 1.023, 1.019, 1.016, 1.016, 1.009
- Urea clearance (%): 87, 85, 73, 77, 75, 94, 85, 85, 10.5, 94
- Protein (%): 0.3, 0.1, 0.12, 0.02
- Urine: RBC, Papilledema, Hemorrhages, Exudate Angiospasm

- Time (years): OPR, 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13

Am J Surg 1948; 75: 48-68
Effects of Renal Sympathetic Nerve Activity on Renal Function

- **Renin secretion rate**
  - $\beta_1$ - adrenoceptor

- **Tubular sodium reabsorption**
  - $\alpha_{1B}$ - adrenoceptor

- **Renal blood flow**
  - $\alpha_{1A}$ - adrenoceptor

DiBona GF, Kopp UC. *Physiol Rev* 77:75-197, 1997
Renal DNX: prevents reflex induced renin secretion

Renal NE Concentration After Renal DNX

Residual renal NE concentration 29% of control at 24-32 days after DNX

**Renal Denervation**

**Preclinical Efficacy and Safety**

- Extensive research in >300 swine
- **Effectiveness:**
  - Statistically significant reduction in renal tissue NE
- **Safety:**
  - Verification testing included angiography, gross pathology, histopathology, & clinical pathology at 7, 30, 60, and 180 days
  - Intact endothelium by 7 days
  - Vascular healing observed at 30 and 60 days; by 180 days, arteries were well healed (no inflammatory cells) – treatment sites were considered sterile and stable
  - No stenosis or luminal reduction seen in any treated artery through 180 days

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**Data on file. Medtronic, Inc.**
Porcine Histology at 7 and 90 days

- 7-days: Circumferential nerve damage with minimal effect on artery; Less injury with NW 2013 formulation
- 90-days: Nerves covered in fibrous connective tissue; arteries look healthy
Overactive SNS is Driver for Resistant HTN

G. Sangiorgi et al., TCT 2012
Renal Denervation by RF Ablation
Related Changes in Underlying Physiology

<table>
<thead>
<tr>
<th></th>
<th>Baseline</th>
<th>1 mo</th>
<th>Δ</th>
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</thead>
<tbody>
<tr>
<td><strong>Office BP</strong></td>
<td>161/107</td>
<td>141/90</td>
<td></td>
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<tr>
<td>(mmHg)</td>
<td></td>
<td></td>
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<tr>
<td><strong>Renal NE spillover</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>- left kidney</td>
<td>72</td>
<td>37</td>
<td>-48%</td>
</tr>
<tr>
<td>- right kidney</td>
<td>79</td>
<td>20</td>
<td>-75%</td>
</tr>
<tr>
<td>(ng/min)</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td><strong>Total body NE spillover</strong></td>
<td>600</td>
<td>348</td>
<td>-42%</td>
</tr>
<tr>
<td>(ng/min)</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td><strong>Plasma Renin</strong></td>
<td>0.3</td>
<td>0.15</td>
<td>-50%</td>
</tr>
<tr>
<td>(µg/l/hr)</td>
<td></td>
<td></td>
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<tr>
<td><strong>Renal Plasma flow</strong></td>
<td>719</td>
<td>1126</td>
<td>57%</td>
</tr>
<tr>
<td>(ml/min)</td>
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</tbody>
</table>

LV Mass (cMRI) dropped 7% (from 78.8 to 73.1 g/m²) from baseline to 12 months

Schlaich et al. NEJM. 2009; 36(9): 932-934.
Ablation of Renal Afferent Nerves: effect on muscle sympathetic nerve activity in a patient with Resistant hypertension

Baseline | 30 days FU | 12 M FU
---|---|---
ECG | | |
BP | | |
MSNA | 56 bursts/min | 41 bursts/min | 19 bursts/min

Schlaich et al. NEJM 2009;36:932-934
Targeting Renal Nerves

- Nerves arise from T10-L2
- The nerves arborize around the artery and primarily lie within the adventitia
Catheter-based RDN Therapy: Ardian and more

- Standard interventional technique
- 4-6 two-minute treatments per artery
- Proprietary RF Generator
  - Automated
  - Low-power
  - Built-in safety algorithms

COV: One Shot STJ: EnligHTN RECOR BSX: Vessix KONA and more...
Catheter-based Renal Denervation: Staged Clinical Evaluation

- First-in-Man ✓
- Series of Pilot studies ✓
- Symplicity HTN-2
  - Initial Randomized Clinical Trial
- Symplicity HTN-3
  - US PMA Randomized Clinical Trial (completed)
- Registries, Symplicity GLOBAL, ACC, LBCT, new techniques

Symplicity HTN-1
Extended follow-up
Catheter-based Renal Denervation: Staged Clinical Evaluation

First-in-Man ✓

Series of Pilot studies ✓

Symplicity HTN-1
Extended follow-up

Symplicity HTN-2
Initial Randomized Clinical Trial

Symplicity HTN-3
US PMA Randomized Clinical Trial (completed)

Registries, Symplicity GLOBAL, ACC, LBCT
Percutaneous renal denervation in patients with treatment-resistant hypertension: final 3-year report of the Symplicity HTN-1 study

Henry Krum, Markus P Schlaich, Michael Böhm, Felix Mahfoud, Krishna Rocha-Singh, Richard Katholi, Murray D Esler

Catheter-based Renal Denervation: Staged Clinical Evaluation

- First-in-Man ✓
- Series of Pilot studies ✓

Symplicity HTN-1
Extended follow-up

Symplicity HTN-2
Initial Randomized Clinical Trial

Symplicity HTN-3
US PMA Randomized Clinical Trial (ACC LBCT, NEJM)

Global Symplicity Registry (ACC LBCT)
Time course of office BP change

RDN
△ from Baseline (mmHg)

Control
△ from Baseline (mmHg)

† p<0.0001 for between-group comparisons
†† p=0.002 for between-group comparisons
††† p=0.005 for between-group comparisons
Two-way repeated measures ANOVA, p=0.001

Catheter-based Renal Denervation: Staged Clinical Evaluation

First-in-Man ✓

Series of Pilot studies ✓

Symplicity HTN-2
Initial Randomized Clinical Trial

Symplicity HTN-3
US PMA Randomized Clinical Trial (ACC LBCT)

Global Simplicity Registry (ACC LBCT)
Renal Denervation Fails in SYMPPLICITY HTN-3

Michael O'Riordan
January 09, 2014

MINNEAPOLIS, MN — The SYMPPLICITY HTN-3 trial, a phase 3 study testing catheter-based renal denervation for the treatment of resistant hypertension, failed to achieve its primary efficacy end point, according to a statement released by Medtronic.1

Despite no safety concerns, the study, which randomized 535 treatment-resistant hypertension patients, failed to show that treatment with the investigational procedure resulted in a
Symplicity HTN 3 - Primary efficacy endpoint

-2.39 (-6.89, 2.12), \( P = 0.255 \) (Primary analysis with 5 mm Hg superiority margin)

- Did not meet primary efficacy endpoint
Lessons Learned from SYMPLICITY HTN-3

HTN-3 Factors Identified

- Procedural
- Medications
- Study Population
Medications

SYMPLICITY HTN-3 Factor Identified

SPYRAL HTN Global Clinical Trial Program

• Obtain off-med data
• Standardize meds
• No max dose titration
• Measure adherence
Were there frequent drug changes between baseline and 6 months of follow up?

Protocol mandated:

*Maximum* doses and
*No* medication changes

~40% of patients *underwent* medication changes*

69% of first medication changes were medically necessary

*Changes included class or dose*
Reconstruction on a chromatogram of the protonated or deprotonated drugs after liquid chromatography high resolution tandem mass spectrometry (LC–HR–MS/MS) analysis. Arrows indicate retention times, at which drug should appear. Dashed lines represent background noise. In this patient example 3 out of 6 (50%) agents were taken as prescribed.
Adherence After RDN

**A** Responder office SBP

- **Baseline**:
  - n=63
  - 81.7%
- **6 months**:
  - n=63
  - 79.2%

\[ p=0.174 \]

**B** Non-responder office SBP

- **Baseline**:
  - n=37
  - 90.6%
- **6 months**:
  - n=37
  - 83.4%

\[ p=0.006 \]

Ewen et al., Clin Res Cardiol (2015)
### SYMPLICITY HTN-3 Factor Identified

**Medications**

- Obtain off-med data
- Standardize meds
- No max dose titration
- Measure adherence

**Study population**

- Less severe HTN
- Fewer prescribed meds
- Focus on ABPM
- Patients from across globe
- Avoid changing patient behavior

### SPYRAL HTN Global Clinical Trial Program
Change in Blood Pressure in African-Americans vs Non-African-Americans

Kandzari et al., 2014 submitted (Symplicity HTN-3), Hotline EurpPCR
Reduced Effect of Percutaneous Renal Denervation on Blood Pressure in Patients With Isolated Systolic Hypertension

Sebastian Ewen, Christian Ukena, Dominik Linz, Ingrid Kindermann, Bodo Cremers, Ulrich Laufs, Stefan Wagenpfeil, Roland E. Schmieder, Michael Böhm, Felix Mahfoud

![Graph](Ewen et al., Hypertension 65: 193-199, 2015)
**SPYRAL HTN Global Clinical Trial Program**

**SYMPLICITY HTN-3 Factor Identified**

- **Medications**
  - Obtain off-med data
  - Standardize meds
  - No max dose titration
  - Measure adherence

**Study population**

- Less severe HTN
- Fewer prescribed meds
- Focus on ABPM
- Patients from across globe
- Avoid changing patient behavior

**Procedural**

- Symplity Spyral™ catheter
- Main and branch vessel treatment
- Experienced proceduralists

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**SPYRAL HTN**
Office BP Response by Number of Ablation Attempts

Kandzari et al., Eur Heart J, 2014  (Symplicity HTN-3)
BP Response by Circumferentiality of Ablation

Kandzari et al., Eur Heart J, 2014 (Symplicity HTN-3)
Renal denervation in 2015 – 7 CE-marked devices
Renal nerves may have a positional bias on radial distance from arterial lumen: distal nerves are closer.

Prior concept – Uniform radial distribution

Current concept – Non-uniform radial distribution

Combined Branch and Main Artery Treatment

Mahfoud et al., JACC 2015 in press
SPYRAL HTN Global Clinical Trial Program

First Phase Includes
Two Parallel Trials
20 Sites Globally

SPYRAL HTN–OFF MED
- 100 patients
- Sham RCT (1:1)
- Main body and branch ablation
- No specific baseline medication requirement
- Compare ABPM change at 3 months
- QOL to be measured

SPYRAL HTN–ON MED
- 100 patients
- Sham RCT (1:1)
- Main body and branch ablation
- No max tolerated dose
- Compare ABPM change at 3 months
- QOL to be measured

Second Phase

SPYRAL HTN Pivotal
- Based on OFF/ON trial results
- Cost effectiveness data/QOL to be measured
Kona Medical *Surround Sound*® Hypertension Therapy
Non-Invasive Renal Denervation

1. Imaging and therapy ultrasound positioned beneath patient
2. Ultrasound imaging used to identify renal artery
3. External ultrasound energy guided by ultrasound image and motion tracking
4. Focused ultrasound energy administered in treatment “pattern” to ablate nerves located outside of artery
5. Energy field surrounds artery, ablates renal nerves

Note: Kona Surround Sound Hypertension Therapy is investigational and not approved for sale
The future... What is planned?
Is diet and exercise just a big waste of time?

• Yes
• No
• Don’t know
Staying active

If you are inactive, you are more likely to have a heart attack than someone who is active.

Being active provides long term benefits for your heart health and general health. It helps control your weight, reduce blood pressure and cholesterol and improve your mental health – helping you to look and feel great.

How do I get started?

Set yourself a goal to build up to at least 30 minutes of moderate physical activity on five or more days a week. Moderate physical activity makes you breathe more heavily than normal and makes you warmer.

If 30 minutes is too much for you at the moment, build up slowly by:

- starting with ten minutes activity at least three times a day and start slowly at a level that suits you
- gradually building up the time and frequency until 30 minutes feels easier
Physical activity

[Hyperlink to Evidence Statements & Narratives]

5.1.7 People at high risk of or with CVD should be advised to take 30 minutes of physical activity a day, of at least moderate intensity, at least 5 days a week, in line with national guidance for the general population\textsuperscript{10}.
## Activities Programme
### July - September 2011

<table>
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<th>Mon</th>
<th>Tue</th>
<th>Wed</th>
<th>Thur</th>
<th>Fri</th>
<th>Sat</th>
<th>Sun</th>
</tr>
</thead>
<tbody>
<tr>
<td>12.00pm Tai Chi</td>
<td>9.30am Thighs, Bums &amp; Tums</td>
<td>9.30am Crèche</td>
<td>9.30am AK Dance</td>
<td>6.00am Youth Drop-in</td>
<td>10.00am Yoga</td>
<td>1.00pm Karate</td>
</tr>
<tr>
<td>5.00pm Crèche</td>
<td>6.00pm Jogging Network</td>
<td>9.30am Body Combat</td>
<td>6.00pm Crèche</td>
<td>11.00am Zumba</td>
<td>11.00am Street &amp; Cheer</td>
<td>12.00pm Street &amp; Cheer</td>
</tr>
<tr>
<td>5.00pm Thighs, Bums &amp; Tums</td>
<td>6.00pm Karate</td>
<td>10.00pm Mini Music Makers</td>
<td>6.00pm Aerobics</td>
<td>12.00pm Street &amp; Cheer</td>
<td>12.00pm Street &amp; Cheer</td>
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<tr>
<td>7.00pm Crèche</td>
<td>5.00pm Street Dance</td>
<td>1.00pm Mini Kickers Under 5 years</td>
<td>7.00pm Crèche</td>
<td>7.00pm Thighs, Bums &amp; Tums</td>
<td>7.00pm Thighs, Bums &amp; Tums</td>
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<tr>
<td>7.00pm Body Combat</td>
<td>7.00pm Body Step</td>
<td>6.00pm Crèche</td>
<td>7.00pm Crèche</td>
<td>7.00pm Thighs, Bums &amp; Tums</td>
<td>7.00pm Thighs, Bums &amp; Tums</td>
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### Gym Inductions
- A gym induction must be completed prior to Gym usage.
- Monday 7.00pm
- Tuesday 9.30am
- Wednesday 7.00pm
- £3.50 Disc

### All classes only £2.25 Disc/£4.40 Disc
Delivering Health: An Alliance between the Royal College of Physicians and Surgeons of Glasgow (RCPSG) and Rangers and Celtic Football Clubs.
Football Health Glasgow

- Staffing:
  - At Ibrox/Parkhead grounds –
  - Coaching staff, medical staff, nurse, dietician, integration with present/former players
  - NHS staff already identified and enthusiastic
  - RCPSG support – data, audit, statistics, long term support
Football Health Glasgow

• Pilot project - introduce a health programme running over 10 weeks via sessions for 20 participants at each club.

• Measurements of weight, blood pressure, cholesterol at start and end of 10 week programme

• Review planned 1 year after end of programme
Weight

P < 0.001

Total cholesterol

Results of Celtic Rangers Football Health Study

Systolic BP

p=NS

Results of Celtic Rangers Football Health Study

![Bar graph showing diastolic blood pressure (BP) over time. The graph includes columns for Start, 3 months, and 15 months, with a note that p=NS.]

Sustained benefits of a health project for middle-aged football supporters, at Glasgow Celtic and Glasgow Rangers Football Clubs

A.J.B. Brady¹*, C. Perry², D.L. Murdoch³, and G. McKay⁴

¹Department of Medical Cardiology, Glasgow Royal Infirmary, UK; ²Department of Medicine, Western Infirmary, Glasgow, UK; ³Department of Cardiology, Southern General Hospital, Glasgow, UK; and ⁴Department of Medicine, Glasgow Royal Infirmary, UK

Introduction

Middle-aged men in the West of Scotland are at high risk of cardiovascular and other diseases. The average life expectancy in parts of Glasgow for men is 64 years, >10 years fewer than affluent parts of England.¹ It is well known that men from this age group are difficult to attract to health programmes, and rarely comply with and continue health-modifying behaviour.²,³ At a meeting between the Royal College of Physicians and Surgeons of Glasgow (RCPSG), and Celtic and Rangers Football Clubs, it was agreed that a pilot study would be undertaken to examine whether this most difficult social group could be addressed in a health programme based at the main Glasgow football clubs. The hypothesis was that the life-long devotion and involvement with the individual’s club could be harnessed to effect the real change in lifestyle and health choices.

The fundamentals of the programme were to develop and to sustain change in the basics of health—diet and exercise. The programme would be based at Ibrox Stadium for Rangers supporters and at Celtic Park for Celtic followers. Obesity, lack of exercise, and poor diet were identified as principal targets for intervention.

*Corresponding author. Email: a.j.brady@clinmed.gla.ac.uk
Football Fans in Training

Get fit, shed a few pounds and become more active with YOUR SPL club.

Are you:
- Male?
- Aged 35-65?
- Trouser waist over 38”?

Do you want to:
- Get fitter?
- Lose some weight?

£2.5M grant

2000 men, cluster cohort design.
Results
A gender-sensitised weight loss and healthy living programme for overweight and obese men delivered by Scottish Premier League football clubs (FFIT): a pragmatic randomised controlled trial

Prof Kate Hunt PhD, Prof Sally Wyke PhD, Cindy M Gray PhD, Prof Annie S Anderson PhD, Adrian Brady MD, Christopher Bunn PhD, Prof Peter T Donnan PhD, Prof Elisabeth Fenwick PhD, Eleanor Grieve MPH, Jim Leishman BSc, Euan Miller MA, Prof Nanette Mutrie PhD, Petra Rauchhaus BSc, Alan White PhD, Prof Shaun Treweek PhD

Summary

Background
The prevalence of male obesity is increasing but few men take part in weight loss programmes. We assessed the effect of a weight loss and healthy living programme on weight loss in football (soccer) fans.
Weight loss (%)

Adjusted between-group difference 12 weeks: 4.71% (CI 5.44, 3.98) p<.0001

Adjusted between-group difference 12 months: 4.36% (CI 5.08, 3.64) p<.0001

Weight loss over time

Lower blood pressure

Systolic (mmHg)
- Adjusted between-group difference 12 weeks: 4.51 (CI 6.36, 2.67), p<.0001
- Adjusted between-group difference 12 months: 2.27 (CI 4.01, 0.54), p=.0171

Diastolic (mmHg)
- Adjusted between-group difference 12 weeks: 2.51 (CI 3.71, 1.32), p<.0001
- Adjusted between-group difference 12 months: 1.36 (CI 2.48, 0.24), p=.0102

(Errow bars represent 95% confidence intervals)
Increased self esteem

Adjusted between-group difference 12 weeks: 0.19 (CI 0.14, -0.24) p<.0001

Adjusted between-group difference 12 months: 0.12 (CI 0.07, 0.17) p<.0001

The next challenge…

BHF £0.25M
Children 11-18 Diet and exercise

Focused approach
  – St Mungo’s Academy, Glasgow UK
Global Football Health

Preliminary discussions:

Tottenham Hotspur
Everton
Fulham

Barcelona, Spain
DC United, Washington, USA
Baltimore Blast, Baltimore, USA
Kingfisher East Bengal FC, Kolkata, India

Ajax, the Netherlands
Two rugby clubs in New Zealand
Conclusions

Diet and exercise are fundamental

Delivery and sustainability is crucial