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Changes in blood pressure after crossover to ultrasound renal denervation

Michael J. Bloch[1]*, MD; Michel Azizi[2], MD, PhD; Ajay J. Kirtane[3], MD, SM; Felix Mahfoud[4-6], MD, MA; Andrew S.P. Sharp[7], MD; Maureen McGuire[8], PhD; Candace K. McClure[9], PhD; Michael Weber[10], MD; on behalf of the RADIANCE investigators

**Corresponding author: University of Nevada School of Medicine, Renown Vascular Care, Renown Institute for Heart and Vascular Health, 1155 Mill Street, Reno, NV 89502, USA. E-mail: michael@bluesprucemed.com*

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Ultrasound renal denervation (uRDN) was demonstrated to lower ambulatory systolic blood pressure (BP) versus a sham procedure at 2 months post-intervention in patients with mild to moderate hypertension (HTN)[1,2] and resistant HTN[3]. While background medications were strictly controlled in these randomised studies, it is important to demonstrate the BP-lowering effect of uRDN in patients treated with antihypertensive medications (AHMs) prescribed by clinicians under unblinded conditions, reflecting a "real-world" setting.

The current analysis included pooled data from the 3 international, multicentre, randomised sham-controlled trials of the RADIANCE[1-3] programme (ClinicalTrials.gov: NCT02649426 and NCT03614260), which compared changes in BP in patients with HTN who received either uRDN or a sham procedure. A list of the study investigators and lead coordinators can be found in **Supplementary Appendix 1**. All 3 studies required patients to be between 18 and 75 years of age, to have an estimated glomerular filtration rate (eGFR) of ≥40 mL/min/1.73 m^2, and a suitable renal artery anatomy. The trials included patients with mild to moderate HTN on 0-2 AHMs[1,2] or patients with resistant HTN despite ≥3 prescribed AHMs[3]. Patients were either taken off medications[1,2] or were stabilised on a triple pill[3] for 4 weeks prior to randomisation. Patients were randomised 1:1[1,2] or 2:1[2] if their daytime ambulatory BP (dABP) remained ≥135/85 mmHg.

Patients were to remain off additional AHMs throughout the first 2 months (primary endpoint ascertainment) of follow-up. After 6 months, AHMs were prescribed per the treating physician's standard of care.

Patients were eligible to crossover to uRDN ≥6 months after randomisation to sham treatment or after failed uRDN if they had a requalifying (crossover baseline) daytime ambulatory systolic BP (dASBP) ≥135 mmHg and/or daytime ambulatory diastolic BP ≥85 mmHg despite the addition of AHMs. After the crossover procedure, AHMs could be adjusted at the physician's discretion. Patients returned for follow-up visits, which included office BP measurement, ambulatory BP monitoring, review of medication use and assessment of safety events, at 2, 6, and 12 months after their uRDN crossover procedure. Adverse events were adjudicated according to definitions used in the RADIANCE-HTN trials, as previously reported[1-3].

Linear mixed models for repeated measures were used to assess covariate-adjusted changes in number of AHMs and BP parameters up to 12 months after the crossover procedure. Fixed-effect terms included study and visit; crossover baseline BP and the number of AHMs were also included as fixed effects in the BP assessments. Also, changes in BP from crossover baseline up to 12 months are shown as unadjusted mean±standard deviation.

This analysis included 92/213 (43.2%) patients who received crossover uRDN: 91 patients were initially randomised to sham treatment, and 1 patient was initially randomised to uRDN but never received treatment. The average time from randomisation to crossover was 23.8±9.3 months. The average age was 53.7±9.2 years; 31.5% were female, and 76.1% were white. At crossover baseline, the mean dASBP of patients was 148.5±16.9 mmHg and the mean office systolic BP (OSBP) was 145.8±11.8 mmHg while being on 1.8±1.6 AHMs (median 2.0 [range 0.0-6.0]).

After crossover to uRDN, there were no significant changes in the number of AHMs: 0.0±0.6, 0.0±0.6, and 0.1±1.1 at 2, 6, and 12 months, respectively. The decrease in dASBP and office systolic BP over 12 months was –9.2 mmHg

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(95% confidence interval [CI]: –12.0 to –6.4; p<0.001) and –5.6 mmHg (95% CI: –8.5 to –2.7; p<0.001), respectively **(Table 1)**. dABP was controlled (<135/85 mmHg) in 44.0% (37/84), 45.6% (31/68), and 39.1% (25/64) of patients at crossover 2-, 6-, and 12-month follow-ups, respectively. Office BP control (<140/90 mmHg) was achieved in 33.7% (28/83), 30.4% (21/69), and 23.0% (14/61) of patients at each respective follow-up visit.

There was 1 death at 21 days after crossover, which was adjudicated as not related to the device or procedure.

This analysis demonstrated consistent BP lowering with subsequent uRDN in patients with persistent uncontrolled HTN after being initially randomised to a sham procedure despite receiving a mean of 1.8 AHMs. These results build on those previously demonstrated with uRDN in the double-blind, sham-controlled trials, in which medications were held stable at 2 months[1-3], and longer-term data, in which medications were added back in in a standardised fashion[4]. Pharmacological observational studies have shown that a reduction of 5 mmHg in OSBP is associated with a 10% reduction in major cardiovascular events, which suggest these reductions are clinically meaningful[5].

Limitations to this analysis include that the results are observational and the reasons why eligible patients did not crossover were not captured. In addition, not all patients had reached their 12-month follow-up ascertainment after crossover uRDN. Background medication use was not standardised, and medication adherence was not systematically measured, reflective of real-world HTN management. It is possible that patients and/or physicians intentionally did not change their medications prior to crossover so they would be eligible for uRDN. While each of these limitations may add an element of uncertainty to the findings presented here, the findings increase the external validity of the results[5].

In conclusion, patients who crossed over to open-label uRDN had statistically significant and clinically meaningful reductions in BP without an increase in medication burden.

Authors' affiliations

1. Department of Medicine, University of Nevada School of Medicine and Renown Vascular Care, Renown Institute of Heart and Vascular Health, Reno, NV, USA; 2. Université Paris Cité, Paris, France and Hypertension Department and DMU CARTE, AP-HP, Hôpital Européen Georges-Pompidou, Paris, France and INSERM, CIC1418, Paris, France; 3. Columbia University Irving Medical Center/New York-Presbyterian Hospital and the Cardiovascular Research Foundation, New York, NY, USA; 4. Department of Cardiology, University Heart Center, University Hospital Basel, Basel, Switzerland; 5. Cardiovascular Research Institute Basel (CRIB), University Heart Center, University Hospital Basel, Basel, Switzerland; 6. Institute for Medical Engineering and Science, Massachusetts Institute of Technology, Cambridge, MA, USA; 7. University

Table 1. Change in daytime ambulatory and office blood pressure at crossover visits adjusting for study, visit, crossover baseline blood pressure, and number of antihypertensive medications.

	Difference: CO month 2 – CO baseline	Difference: CO month 6 – CO baseline	Difference: CO month 12 – CO baseline	Overall change from CO baseline without treatment arm by visit interaction	Overall change from CO baseline with treatment arm by visit interaction
Daytime ambulatory systolic BP	–10.2±13.2 (84)* –9.9 (–13.0 to –6.7; <0.001)¶	–10.1±15.9 (68)* –9.0 (–12.4 to –5.6; <0.001)¶	–9.5±16.1 (64)* –8.3 (–11.8 to –4.7; <0.001)¶	–9.2 (–12.0 to –6.4; <0.001)¶	–9.0 (–11.9 to –6.2; <0.001)¶ 0.623†
Daytime ambulatory diastolic BP	–6.5±8.6 (84)* –6.1 (–8.1 to –4.1; <0.001)¶	–6.9±10.4 (68)* –5.8 (–7.9 to –3.6; <0.001)¶	–6.4±10.4 (64)* –5.6 (–7.8 to –3.3; <0.001)¶	–5.9 (–7.7 to –4.1; <0.001)¶	–5.8 (–7.6 to –4.0; <0.001)¶ 0.867†
Nighttime ambulatory systolic BP	–10.4±13.5 (84)* –9.9 (–12.9 to –6.9; <0.001)¶	–7.4±14.5 (68)* –6.4 (–9.6 to –3.2; <0.001)¶	–6.8±15.4 (63)* –6.1 (–9.5 to –2.8; <0.001)¶	–7.9 (–10.7 to –5.2; <0.001)¶	–7.5 (–10.2 to –4.7; <0.001)¶ 0.015†
Nighttime ambulatory diastolic BP	–6.9±9.7 (84)* –6.5 (–8.4 to –4.6; <0.001)¶	–5.4±10.1 (68)* –4.6 (–6.7 to –2.6; <0.001)¶	–4.0±10.7 (63)* –3.4 (–5.6 to –1.3; 0.002)¶	–5.2 (–6.8 to –3.5; <0.001)¶	–4.9 (–6.6 to –3.2; <0.001)¶ 0.008†
24-hour ambulatory systolic BP	–10.3±12.5 (84)* –9.8 (–12.8 to –6.8; <0.001)¶	–9.1±14.4 (68)* –8.0 (–11.2 to –4.8; <0.001)¶	–8.6±15.0 (64)* –7.5 (–10.8 to –4.2; <0.001)¶	–8.7 (–11.4 to –6.0; <0.001)¶	–8.5 (–11.2 to –5.7; <0.001)¶ 0.235†
24-hour ambulatory diastolic BP	–6.7±8.4 (84)* –6.2 (–8.1 to –4.3; <0.001)¶	–6.4±9.5 (68)* –5.4 (–7.4 to –3.4; <0.001)¶	–5.6±9.8 (64)* –4.8 (–6.8 to –2.8; <0.001)¶	–5.6 (–7.3 to –3.9; <0.001)¶	–5.5 (–7.2 to –3.8; <0.001)¶ 0.287†
Office systolic BP	–7.3±16.9 (83)* –6.6 (–10.0 to –3.2; <0.001)¶	–4.8±18.9 (69)* –4.1 (–7.8 to –0.4; 0.029)¶	–7.0±18.0 (61)* –5.6 (–9.5 to –1.7; 0.005)¶	–5.6 (–8.5 to –2.7; <0.001)¶	–5.4 (–8.3 to –2.5; <0.001)¶ 0.411†
Office diastolic BP	–5.1±10.8 (83)* –4.6 (–6.8 to –2.4; <0.001)¶	–3.6±11.9 (69)* –2.8 (–5.1 to –0.4; 0.022)¶	–4.0±10.5 (61)* –3.3 (–5.8 to –0.8; 0.010)¶	–3.7 (–5.6 to –1.8; <0.001)¶	–3.5 (–5.5 to –1.6; <0.001)¶ 0.262†

*Unadjusted mean±SD (n). ¶Least squares means (95% CI; p-value). Means from repeated measures model adjusted for study, crossover baseline value, visit, and number of antihypertensive medications at visit. †P-value for visit variable. BP: blood pressure; CI: confidence interval; CO: crossover; SD: standard deviation

College Dublin, Dublin, Ireland; 8. Recor Medical, Palo Alto, CA, USA; 9. NAMSA, Minneapolis, MN, USA; 10. Division of Cardiovascular Medicine, State University of New York, Downstate Medical Center, New York, NY, USA

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Conflict of interest statement

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Supplementary data

Supplementary Appendix 1. RADIANCE-HTN SOLO, RADIANCE-HTN TRIO, RADIANCE II organisation.

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Supplementary data

Supplementary Appendix 1. RADIANCE-HTN SOLO, RADIANCE-HTN TRIO, RADIANCE II organisation.

Investigators and Lead Study Coordinators by Country

RADIANCE II Investigators and Lead Study Coordinators by Country

United States

Minneapolis Heart Institute Foundation, Minneapolis, MN: Yale Wang, Nedaa Skeik, Richard Bae, Amy McMeans, JoAnne Goldman, Rose Peterson. **Ochsner Heart and Vascular Institute, New Orleans, LA:** James Stephen Jenkins, Isabelle Tutor, Michael Harrison, Angel Penning. **Emory University, Atlanta GA:** Chandan Devireddy, Janice Lea, Amanda Fiebach, Claudia Merlin. **Cedars-Sinai Medical Center, Los Angeles, CA:** Florian Rader, Suhail Dohad, Anne Tran, Kirin Bhatia. **The Brigham and Women's Hospital, Boston, MA:** Naomi DL Fisher, Piotr Sobieszczyk, Ian Halliday, Tay Munson. **Saint Lukes Hospital of Kansas City, Kansas City, MO:** Jason Lindsey, Steven Laster, Mathew Bunte, Anthony Hart, Dana King, Jamie Hall. **Deborah Heart & Lung Center, Brown Mills, NJ:** Kintur Sanghvi, Courtney Krathen, Luot Lewis, Ashley Willitts. **Medical University of South Carolina, Charleston, SC:** Thomas Todoran, Jan Basile, Anthony Awkar, Casey Palmer, Anna Tecklenburg. **University of Pittsburgh Medical Center, Pittsburgh, PA:** John Schindler, John Pacella, Matthew Muldoon, MaryJo Albright, Tracy Nicholson. **Southern Illinois University School of Medicine, Springfield, IL:** John Flack, Youseff Chami, Abdul Moiz Hafiz, Emily Starkey, Kristal Adams. **MedStar Washington Health Research, Baltimore, MD:** Nelson Bernardo, Judith Veis, Hayder Hashim, Suman Singh, Donna Whitman. **The University of North Carolina, Chapel Hill, NC:** Rick Stouffer, Alan Hinderliter, Meghan Allen, Tatum Scholl. **Vanderbilt University Medical Center, Nashville, TN:** Pete Fong, James Gainer, Sherron Crook, Ellen Hatchcock. **Penn Medicine, Philadelphia, PA**: Debbie Cohen, Jay Giri, Taisei Kobayashi, Robin Neubauer, Suveeksha Naidu. **Columbia University Medical Center New York, NY:** Ajay J. Kirtane, Jai Radhakrishnan, Candido Batres, Suzanne Edwards. **The Cardiac and Vascular Institute Gainesville, FL:** Matheen Khuddus, Suzanne Zentko, Abby Touchton, Marti Roberson. **Renown Regional Medical Center, Reno, NV:** Michael J. Bloch, Abhilash Akinapelli, Lisa English, Bridget Neumann. **Cardiology PC, Birmingham, AL: F**arrel Mendelsohn, Hutton Brantley, Thomas Cawthon, Susan DeRamus, Wesley Wade. **Bridgeport Hospital, Bridgeport, CT:** Robert Fishman, Edward Tuohy, Jessica LeBlanc, Tina McCurry. **Cleveland Clinic Foundation, Cleveland, OH:** Amar Krishnaswamy, Luke Laffin, Christopher Bajzer, Marilyn Boros, Monica Branche. **University of Utah Medical Center, Salt Lake City, UT:** Josephine Abraham, Anu Abraham, Inge Stijleman. **Stamford Hospital, Stamford, CT:** David Hsi, Scott Martin, Edward Portnay, Maryann Fiebach, Carolina Garavito. **Munson Medical Center, Traverse City, MI:** Todd Adams, Andrew Teklinski, Adam Leech, Patrick Drilling, Lynda Tulik. **Northwestern University, Chicago, IL:** Keith Benzuly, James Paparello, Dan Fintel, Haydee Ramirez, Lauren Kats. **Swedish Medical Center, Seattle, WA:** Paul Huang, MD; Santanu Biswas, Serena Risher, Kristina Pratt. **University of Tennessee, Memphis, Memphis, TN:** Uzoma Ibebuogu, Karen Johnson, William Cushman, Lisa Jones, Leigh Jackson. **Hackensack University, Hackensack, NJ:** David Landers, Tilak Pasala, Thomas Salazer, Peter Canino, Patricia Arakelian. **Northwell Health- New York, NY**: Yi-Ming Yang, Asma Khaliq, Mitchell Weinberg, Yihenew Abetu, Alana Gulliver. **Stony Brook Medicine:** J.P. Reilly. **Massachusetts General Hospital, Boston, MA:** Joseph Garasic. **Franciscan Health, Indianapolis, IN:** Atul Chugh. **Cardiology Associates of North Mississippi, Tupelo, MS:** Barry Bertolet. **WakeMed Clinical Research Institute, Raleigh, NC:** Brian Go**. San Diego Cardiac Center, San Diego, CA:** Raghava Gallapudi. **Sparrow Clinical Research Institute:** Joel Cohn. **University of Colorado, Denver, CO:** Kevin Rogers

United Kingdom

St Barts Health: Manish Saxena, Anthony Mathur, Ajay Jain, Armida Balawon, Oliver Zongo, Christine Topham. **University Hospital of Wales Cardiff:** Andrew Sharp, Richard Anderson, Elizabeth Thompson, Nikki Spiro, Elizabeth Hodges, Jaqueline Holder. **Freeman Hospital Newcastle:** Timothy Ellam, Alan Bagnall, Ralph Jackson, Victoria Bridgett, Peter Wilson. **Kent and Canterbury Hospital:** Neelanjan Das, Timothy Doulton, David Loader, Gemma Hector. **Royal Bournemouth Hospital:** Terry Levy, Clare Bent, Vivek Kodoth, Stephanie Horler, Sara Nix. **Cardiothoracic Centre Basildon University Hospital Essex:** Nicholas Robinson, Firas Al-Janabi, Jeremy Sayer, Sudha Ganesh Iyer, Emily Redman, Jonaifah Ramirez. **Queen Elizabeth University Hospital Glasgow:** Sandosh Padmanabhan

Ireland
University Hospital Galway: Faisal Sharif, Aishah Alhmoudi, Mattia Lunardi, Eileen Coen, Nicola Glynn

Germany
University Clinic of Saarland- Homburg: Felix Mahfoud, Lucas Lauder, Saarraaken Kulenthiran, Christina Koch, Angelika Wachter. **University Clinic Erlangen**: Roland Schmieder, Axel Schmid, Dennis Kannenkeril, Ulrike Heinritz, Kerstin Endres-Frohlich. **Heart Center, Leipzig**: Philipp Lurz, Karl Rommel, Fengler; Martin Petzold , Margit Büttner. **Sana Kliniken Lubeck GmbH**: Joachim Weil, Tolga Agdirlioglu, Tanja Köllner, Jeannine Stephan. **Klinikum Konstanz**: Nikolaos Dagkonakis, Frank Hamann, Ute Ettl, Ulrike Petzsche. **Klinikum Karlsruhe**: Peter Reimer, Martin Hausberg, Ralf Hinrichs, Isabella Di Ponio-Voit. **UKSH Kiel:** Matthias Lutz

France
Hôpital Saint-André – CHU, Bordeaux: Philippe Gosse, Antoine Cremer, Panteleimon Papadopoulos, Julie Gaudissard, Florent Maire. **Hôpital Européen Georges-Pompidou, Paris:** Michel Azizi, Marc Sapoval, Marine Livrozet, Asma Regrag, Valerie Paquet. **CHRU Lille, Lille:** Pascal Delsart, Justin Hennicaux, Coralie Sommeville, Fabien Bertrand.

The Netherlands
Erasmus MC, Rotterdam: Joost Daemen, Melvin Lafeber, Victor Zeijen, Amo Ruiter, Elisabeth Huijskens. **Noordwest Zienkenhuisgroeo – Alkmaar:** Jan van Ramshorst

Belgium
UMC Saint Pierre - Panagiotis Xaplanteris, Rachid Briki, Quentin de Hemptinne**,** Severine Pascal, Katty Renard. **Hopital Civel Marie Curie Charleroi -**Pascal Lefebvre. **ZOL Genk** – Bert Ferdinande

Switzlerland
Hopitaux Universitaries Geneva: Juan F. Iglesias, Georg Ehert, Laetitia Gallego, Kevin Dobretz, Sylviane Bottone

RADIANCE-HTN TRIO Investigators and Lead Study Coordinators by Country

United States

Deborah Heart & Lung Center, Brown Mills, NJ: Kintur Sanghvi, Josh Costello, Courtney Krathan, Luot Lewis, Andrew McElvarr. **Ochsner Heart and Vascular Institute, New Orleans, LA:** John Reilly, Stephen Jenkins Michael Cash, Shannon Williams, Maria Jarvis. **Vanderbilt University Medical Center, Nashville, TN:** Pete Fong, Cheryl Laffer, James Gainer, Mark Robbins, Sherron Crook, Sarita Maddel. **Stamford Hospital, Stamford, CT:** David Hsi, Scott Martin, Edward Portnay, Maryanne Ducey, Suzanne Rose, Elizabeth DelMastro. **NYU Langone Medical Center, New York, NY:** Sripal Bangalore, Stephen Williams, Stanley Cabos, Carolina Rodriguez Alvarez. **Medical University of South Carolina, Charleston, SC:** Thomas Todoran, Jan Basile, Eric Powers, Emily Hodskins, Vijay Paladugu, Anna Tecklenburg. **Emory University, Atlanta GA:** Chandan Devireddy, Janice Lea, Bryan Wells, Amanda Fiebach, Claudia Merlin. **Cedars-Sinai Medical Center, Los Angeles, CA:** Florian Rader, Suhail Dohad, Hyun-Min Kim, Mohammad Rashid. **University of Utah Medical Center, Salt Lake City, UT:** Josephine

Abraham, Theophilus Owan, Anu Abraham, Iran Lavasani, Hailey Neilson. **University of Alabama, Birmingham, AL:** David Calhoun, Thomas McElderry, William Maddox, Suzanne Oparil, Sheila Kinder. **Columbia University Medical Center New York, NY:** Ajay J. Kirtane, Jai Radhakrishnan, Candido Batres, Suzanne Edwards. **Mass General Hospital, Boston, MA:** Joseph Garasic, Doug Drachman, Randy Zusman, Kenneth Rosenfield, Danny Do. **The Cardiac and Vascular Institute Gainesville, FL:** Matheen Khuddus, Suzanne Zentko, James O'Meara, Ilie Barb, Abby Foster, Alice Boyette. **Minneapolis Heart Institute Foundation, Minneapolis, MN:** Yale Wang, Desmond Jay, Nedaa Skeik, Robert Schwartz, Rose Peterson, Jo Anne Goldman. **Drexel University, Philadelphia, PA:** Jessie Goldman, Gary Ledley, Nancy Katof. **The Heart Hospital Baylor Plano, Plano, TX:** Srinivasa Potluri, Scott Biedermann Jacquelyn Ward, Megan White. **The Brigham and Women's Hospital, Boston, MA:** Naomi DL Fisher, Laura Mauri, Piotr Sobieszczky, Alex Smith, Laura Aseltine. **The University of North Carolina, Chapel Hill, NC:** Rick Stouffer, Alan Hinderliter, Eric Pauley, Tyrone Wade. **University Hospitals Cleveland Medical Center, Cleveland, OH:** David Zidar, Mehdi Shishehbor, Barry Effron, Marco Costa, Terence Semenec. **Renown Regional Medical Center, Reno, NV:** Michael J. Bloch, Chanwit Roongsritong, Priscilla Nelson, Bridget Neumann. **University of Pennsylvania**: Debbie Cohen, Jay Giri, Robin Neubauer, Thu Vo. **Franciscan Health Indianapolis**, **Indianapolis, IN:** Atul R. Chugh. **Sutter Medical Center, Sacramento, CA:** Pei-Hsiu Huang, Powell Jose. **Southern Illinois University School of Medicine, Springfield, IL:** John Flack. **Bridgeport Hospital, Bridgeport, CT:** Robert Fishman. **Baptist Health Lexington, Lexington, KY:** Michael Jones. **Munson Medical Center, Traverse City, MI:** Todd Adams. **Cleveland Clinic, Cleveland, OH:** Christopher Bajzer.

United Kingdom

Barts Health NHS Trust, London: Manish, Saxena, Melvin D. Lobo, Anthony Mathur, Ajay Jain, Armida Balawon, Olivier Zongo. **University Hospitals Dorset NHS Foundation Trust, Dorset:** Terry Levy, Clare Bent, David Beckett, Nicki Lakeman, Sarah Kennard. **The Royal Devon and Exeter NHS Foundation Trust, Exeter:** Andrew Sharp, Richard J D'Souza, Sarah Statton, Lindsay Wilkes, Christine Anning. **Mid and South Essex NHS Foundation Trust, Essex:** Jeremy Sayer, Sudha Ganesh Iyer, Nicholas Robinson, Annaliza Sevillano, Madelaine Ocampo. **East Sussex Healthcare NHS Trust, Sussex:** Robert Gerber, Mohamad Faris, Andrew John Marshall, Janet Sinclair, Hayley Pepper. **Imperial College Healthcare NHS Trust, London:** Justin Davies, Neil Chapman, Paula Burak, Paula Carvelli. **Nottingham University Hospitals NHS Trust, Nottingham:** Sachin Jadhav, Jane Quinn.

Germany

Düsseldorf University Hospital, Düsseldorf: Lars Christian Rump, Johannes Stegbauer, Lars Schimmöller, Sebastian Potthoff, Claudia Schmid, Sylvia Roeder. **Sana Kliniken Lübeck GmbH, Lübeck:** Joachim Weil, Lukas Hafer, Tolga Agdirlioglu, Tanja Köllner. **Saarland University Hospital, Homburg:** Felix Mahfoud, Michael Böhm, Sebastian Ewen, Saarraaken Kulenthiran, Angelika Wachter, Christina Koch. **Heart Center, Leipzig:** Philipp Lurz, Karl Fengler, Karl-Philipp Rommel, Kai Trautmann, Martin Petzold. **University Hospital Erlangen, Erlangen**: Roland E. Schmieder, Christian Ott, Axel Schmid, Michael Uder, Ulrike Heinritz, Kerstin Fröhlich-Endres. **Katholisches Klinikum Mainz, Mainz:** Sabine Genth-Zotz, Denise Kämpfner, Armin Grawe, Johannes Höhne. Bärbel Kaesberger. **Freiburg University and Faculty of Medicine, Freiburg:** Constantin von zur Mühlen, Dennis Wolf, Markus Welzel. Gudrun Heinrichs, Barbara Trabitzsch

France

Hôpital Saint-André – CHU, Bordeaux: Philippe Gosse, Antoine Cremer, Hervé Trillaud, Panteleimon Papadopoulos, Florent Maire, Julie Gaudissard. **Hôpital Européen Georges-Pompidou, Paris:** Michel Azizi, Marc Sapoval, Erika Cornu, David Fouassier, Marine Livrozet, Aurélien Lorthioir, Valérie Paquet. **Clinique Pasteur / GCVI, Toulouse:** Atul Pathak, Benjamin Honton, Marianne Cottin, Frédéric Petit. **Hôpital de la Croix Rousse, Lyon:** Pierre Lantelme, Constance Berge, Pierre-Yves Courand, Fatou Langevin. **CHRU Lille, Lille:** Pascal Delsart, Benjamin Longere, Guillaume Ledieu, François Pontana, Coralie Sommeville, Fabien Bertrand.

The Netherlands

Erasmus MC, Rotterdam: Joost Daemen, Lida Feyz, Victor Zeijen, Arno Ruiter, Elisabeth Huyskens. **University Medical Center Utrecht, Utrecht:** Peter Blankestijn, Michiel Voskuil, Zwaantina Rittersma, Helma Dolmans. **Maastricht University Hospital, Maastricht:** A.A. Kroon, W.H. van Zwam, Jeannique Vranken, Claudia de Haan.

Belgium

Cliniques Universitaires Saint-Luc, Brussels: Alexandre Persu, Jean Renkin, Frédéric Maes, Christophe Beauloye, Jean-Philippe Lengelé, Dominique Huyberechts, Anne Bouvier.

Poland

Institute of Cardiology, Warsaw: Adam Witkowski, Andrzej Januszewicz, Jacek Kądziela, Aleksander Prejbisj. **Medical University of Gdansk, Gdansk:** Dagmara Hering, Dariusz Ciecwierz, Milosz J. Jaguszewski, Radoslaw Owczuk, Dariusz Ciecwierz, Milosz J. Jaguszewski.

RADIANCE-HTN SOLO Investigators by Country

United States

Minneapolis Heart Institute Foundation, Minneapolis, MN: Yale Wang, Desmond Jay, Nedaa Skeik, Robert Schwartz. **Cedars-Sinai Medical Center, Los Angeles, CA:** Florian Rader, Suhail Dohad, Ronald Victor. **Deborah Heart & Lung Center, Brown Mills, NJ:** Kintur Sanghvi, Josh Costello, Courtney Walsh. **University of Utah Medical Center, Salt Lake City, UT:** Josephine Abraham, Theophilus Owan, Anu Abraham. **The Brigham and Women's Hospital, Boston, MA:** Naomi DL Fisher, Laura Mauri, Piotr Sobieszczky, Jonathan Williams. **Renown Regional Medical Center, Reno, NV:** Michael J. Bloch, Chanwit Roongsritong. **Medical University of South Carolina, Charleston, SC:** Thomas Todoran, Jan Basile, Eric Powers, Emily Hodskins. **Vanderbilt University Medical Center, Nashville, TN:** Pete Fong, Cheryl Laffer, James Gainer, Mark Robbins. **Ochsner Heart and Vascular Institute, New Orleans, LA:** John Reilly, Michael Cash. **Drexel University, Philadelphia, PA:** Jessie Goldman, Sandeep Aggarwal, Gary Ledley. **Stamford Hospital, Stamford, CT:** David Hsi, Scott Martin, Edward Portnay. **University of Alabama, Birmingham, AL:** David Calhoun, Thomas McElderry, William Maddox, Suzanne Oparil. **Sutter Medical Center, Sacramento, CA:** Pei-Hsiu Huang, Powell Jose. **The Cardiac and Vascular Institute Gainesville, FL:** Matheen Khuddus, Suzanne Zentko, James O'Meara, Ilie Barb. **Mass General Hospital, Boston, MA:** Joseph Garasic, Doug Drachman, Randy Zusman, Kenneth Rosenfield. **Emory University, Atlanta GA:** Chandan Devireddy, Janice Lea, Bryan Wells. **The University of North Carolina, Chapel Hill, NC:** Rick Stouffer, Alan Hinderliter, Eric Pauley. **The Heart Hospital Baylor Plano, Plano, TX:** Srinivasa Potluri, Scott Biedermann. **NYU Langone Medical Center, New York, NY:** Sripal Bangalore, Stephen Williams. **University Hospitals Cleveland Medical Center, Cleveland, OH:** David Zidar, Mehdi Shishehbor, Barry Effron, Marco Costa. **Columbia University Medical Center New York, NY:** Ajay J. Kirtane, Jai Radhakrishnan.

United Kingdom

St. Barts Health NHS Trust, London: Melvin D. Lobo, Manish, Saxena, Anthony Mathur, Ajay Jain.* **The Essex Cardiothoracic Centre, Essex:** Jeremy Sayer, Sudha Ganesh Iyer, Nicholas Robinson, Sadat Ali Edroos. **Royal Bournemouth Hospital, Dorset:** Terry Levy, Amit Patel, David Beckett, Clare Bent. **Hammersmith Hospital, Imperial College Healthcare NHS Trust, London:** Justin Davies, Neil Chapman, Matthew Shun Shin, James Howard. **The Royal Devon and Exeter NHS Foundation Trust, Exeter:** Andrew SP Sharp, Anil Joseph, Richard D'Souza.** **Conquest Hospital, East Sussex NHS Trust, Sussex:** Robert Gerber, Mohamad Faris, Andrew John Marshall, Cristina Elorz.

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Germany

Leipzig Heart Center, Leipzig: Philipp Lurz, Robert Höllriegel, Karl Fengler , Karl-Philipp Rommel. **University Clinic of Saarland, Homburg:** Felix Mahfoud, Michael Böhm, Sebastian Ewen, Jelena Lucic. **University Clinic Erlangen, Erlangen**: Roland E. Schmieder, Christian Ott, Axel Schmid, Michael Uder. **University Clinic Dusseldorf, Dusseldorf**: Christian Rump, Johannes Stegbauer, Patric Kröpil.

France

Hôpital Européen Georges-Pompidou, Paris: Michel Azizi, Marc Sapoval, Erika Cornu, David Fouassier. **Hôpital Saint-André – CHU, Bordeaux:** Philippe Gosse, Antoine Cremer, Hervé Trillaud, Panteleimon Papadopoulos. **Clinique Pasteur / GCVI, Toulouse:** Atul Pathak, Benjamin Honton. **Hôpital de la Croix Rousse, Lyon:** Pierre Lantelme, Constance Berge, Pierre-Yves Courand.

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Belgium

Cliniques Universitaires Saint-Luc, Brussels: Alexandre Persu, Jean Renkin.