*Michael Böhm*

# Perspectives on the latest SYMPLICITY data: An update from the Global SYMPLICITY Registry

The Global SYMPLICITY Registry is a large, multinational registry that is providing valuable insights into the outcomes of patients undergoing renal denervation in 'real-world' settings. With the first data from the trial having been released at American College of Cardiology (ACC) 2014 Scientific Sessions (29–31 March, Washington, DC, USA), *Confluence* spoke to Professor Michael Böhm, Saarland University Hospital, Homburg/Saar, Germany, and Lead Investigator of the study to find out more about the trial, its results and the future of renal denervation.

## Please can you give us a brief overview of the Global SYMPLICITY Patient Registry?

The primary goal of the Global SYMPLICITY Registry (GSR) was to provide safety and effectiveness data on the use of renal denervation in 'real-world' settings. This is important because investigators and patients in the clinic might differ from those involved in clinical trials, which have extensive proctoring and strict adherence to protocols.

The GSR aims to enrol 5,000 patients to provide insights into the long-term outcomes with renal denervation. In this study, patients will be followed up for a period of 5 years. At the ACC Scientific Sessions, the blood pressure reduction and safety results of the first 1,000 patients from the GSR were reported. The majority of patients came from Western Europe, but about one third came from other nations such as Australia, New Zealand, Canada and South Africa, as well as from countries in Asia.

## What differentiates this registry from clinical trials in renal denervation?

The unique feature of the registry is to provide data from the real world in a broad population of patients. This means that the data in the GSR not only covers patients with resistant hypertension, but also those in whom the procedure was carried out due to comorbidities such as arrhythmias and heart failure. Therefore, all together, the GSR provides data on a much broader population than in trials with different levels of blood pressure at baseline and comorbidities. It is important to compare such diverse patient populations with different baseline blood pressures and an array of comorbidities. Such data will help to drive the generation of hypotheses that can be tested in future controlled clinical trials. Furthermore, by looking at such a spectrum of patients, we can have greater confidence in treating the diverse patient populations seen in clinics.

## How should data from the GSR be viewed alongside data from the SYMPLICITY-HTN studies?

The first difference is geographical; the GSR provides data in countries where the technique is introduced. Therefore, the investigators in the GSR have more experience than the SYMPLICITY HTN-3 study investigators because in America the technique is not yet approved. The vast majority of HTN-3 investigators performed less than 5 procedures, which then immediately were incorporated in the SYMPLICITY HTN-3 trial. This might be one reason why the reduction in blood pressure in the GSR was slightly more pronounced than in the HTN-3 study.

## Will the registry also collect data for other diseases characterized by elevated sympathetic drive? If so, what information do you hope to gain from the GSR that can inform the use of renal denervation in treating different conditions?

Several patients with heart failure and arrhythmia will be included in the GSR. Long-term follow-up of

these patients will help us to judge whether there is potential to use this technology beyond hypertension. We also expect to be able to analyze information on the impact of different comorbidities of hypertension.

## What long-term data have been shown so far from the registry, and how will long-term data from the registry inform clinical practice?

At the ACC, the 6-month data from the first 1,000 patients enrolled in the GSR were presented. The next milestone will be the presentation of the 12-month data for approximately 1,000 patients and potentially the 6-month data for 1,500–2,000 patients. These analyses will also include endpoints. However, the influence of renal denervation on the rate of adverse events cannot be judged because the registry does not provide information on a control group.

Patients were included not only for office blood pressure, but also for high results from ambulatory blood pressure monitoring (ABPM). Furthermore, the decision to treat these patients with renal denervation followed clinical decisions based on resistance to pharmacotherapies or patient preference. As the majority of these patients were treated according to the guidelines, these data provide a picture of how they are responding in the clinic under standard operating procedures.

## In future, how can teams work together more effectively to identify and treat patients who may benefit from renal denervation?

Renal denervation programmes should be collaborations between hypertension specialists, interventional cardiologists and general practitioners, who identify patients at risk and arrange for their referral to a specialist renal denervation centre.

## What will the impact of the HTN-3 data be on the registry?

As the GSR is independent of the HTN-3 trial, we do not think there will be any impact. We believe that the GSR will help to provide better insights into renal denervation and allows for an alternative strategy for data generation avoiding some of the limitations from HTN-3.

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