


tion for patients with severe aortic stenosis. EuroIntervention 2012;8: 258–66.

[20] Bourantas CV, Farooq V, Onuma Y, Piazza N, Van Mieghem NM, Serruys PW. Transcatheter aortic valve implantation: new developments and up-

ition statement from the European Association of Cardio-Thoracic Surgery (EACTS) and the European Society of Cardiology (ESC), in collabora-
tion with the European Association of Percutaneous Cardiovascular Inter-

[22] Dewey TM, Brown D, Ryan WH, Herbert MA, Prince SL, Mack MJ. Reliability of risk algorithms in predicting early and late operative out-


The GARY Registry: a new paradigm of outcomes assessment

David Holmesa and Michael Mackb,*

a Mayo Clinic, Rochester, MN, USA
b Baylor Scott & White Health, Dallas, TX, USA

* Corresponding author. 1100 Allied Dr, Plano, TX 75075, USA. Tel: +1-469-800-6200; fax: +1-972-4905457; e-mail: michael.mack@baylorhealth.edu (M. Mack).

Keywords: TAVI • Registries • Aortic valve

The German Aortic Valve Registry (GARY) published in this issue of the journal represents a new paradigm in outcomes assessment of interventional and surgical procedures from a number of important perspectives [1]. Firstly, it is a precedent-setting collaboration of multiple stakeholders including the societies of cardiology (DGK) and cardiac surgery (DGTHG), the German Heart Foundation, but most importantly a patient organization, Deutsche Herzstiftung with unrestricted support from industry as well as the two professional societies. Secondly, the registry reports comprehensive outcomes of all patients undergoing surgical aortic valve replacement and transcatheter aortic valve replacement from 78 centres in Germany and includes 55% of all aortic valvular (AV) procedures in that country. Thirdly, included in this outcomes assessment for the first time is the quality of life measurement at 1 year, a critically important outcome metric for all patients but particularly so for this elderly population who are markedly symptomatic.

So, why are population-based multistakeholder registries so important? It is of course important that we have solid evidence of device performance and application outside of the strictly controlled boundaries of randomized trial settings. It is reassuring to know from this report that the outcomes in the ‘real world’ of clinical practice are largely similar to those obtained in the trial setting. But more importantly, it establishes the information platform for longer-term follow-up in a larger group of patients with plans to collect outcomes out to 5 years on 80,000 patients in Germany treated for aortic stenosis over a 5-year period from 2011 through 2015. There are a number of important uses of this information other than outcomes assessment. Firstly, since this registry captures outcomes of both surgery and transcatheter therapy, comparative effectiveness research can be performed with hopefully identification of specific subgroups, which may respond better to one therapy or another. Second is the development and implementation of an efficient infrastructure for performance of quality
improvement and peer review within participating institutions. Third is the ability to perform post-market approval device surveillance. With many new devices coming to market, a robust registry can serve as the benchmark for device performance, the so-called objective performance criteria (OPC). Fourth, as has been done in Sweden with the SCAAR national registry is the ability to perform randomized trials within the registry format on a more timely and cost-efficient basis than the traditional independent, free-standing, randomized, controlled trial [2, 3]. The fifth potential benefit of a population-based registry of this size and scope is the ability to establish risk/benefit algorithms. This is of particular importance with TAVI procedures. Although a number of risk predictive algorithms have been developed and validated for surgical aortic valve replacement such as Logistic EuroSCORE, EuroSCORE II and the Society of Thoracic Surgeons (STS) Predicted Risk of Mortality, none have proved to be directly translatable to TAVI. GARY has taken the initial steps towards risk adjustment with the German AV score [4]. Ideally what can be developed are a surgical aortic valve replacement predictive risk algorithm and a TAVI specific one. Since the variables impacting outcomes are likely different between the two procedures, two separate and specific algorithms would be developed. The relative risk of a specific patient for either procedure could then be determined and used to inform patients and optimize outcomes. Other uses of a national registry such as GARY include determination of a learning curve and the volume-outcome relationship between high-volume and low-volume centres.

The demand for public reporting of centre and operator outcomes is increasing (http://www.consumerreports.org/content/cro/en/consumer-reports-magazine/z2014/August). The availability of clinical databases such as GARY, with professional society involvement optimizes the potential to obtain the highest quality of clinically relevant data and report statistically significant outcomes while minimizing bias.

The final benefit of national registries such as GARY is the ability to create an international network of registries in a distributed framework so that a truly global device surveillance infrastructure is formed. Such an international consortium has been created with orthopaedic device procedures and was instrumental in identifying at a relatively early stage the ‘metal on metal’ hip prosthesis safety signal that required a large international population to detect [5]. Indeed, the GARY Registry is in the early stages of collaboration with national registries in France, the UK, Canada and the USA to form such a network, the International Consortium of Cardiovascular Registries under a grant from the Food and Drug Administration in the USA [6–9].

There are, however, some concerns about registries in general including adjudication of data, completeness of reporting and, perhaps most importantly, the issues of unmeasured confounding variables that may impact patient selection. These concerns are also present in the unique GARY Registry. There are other issues in addition: the registry captures only 55% of all patients undergoing aortic valve procedures in Germany; participation is voluntary and not mandatory and requires individual patient informed consent. Important questions are why are the other centres not participating, and is this report truly representative of the national experience as a whole? A second question relates to sustainability. The registry has been funded until now by the professional societies and industry and covers 5 years of procedures with 5 years of follow-up. At the end of that time, how will the registry sustain itself? Future funding for the ability to apply all the uses of the registry enumerated above is critical. From whence will this funding come? As the first two Chairs of the STS/ACC TVT Registry in the USA, we wrestle constantly with this issue of creating multistakeholder and societal value and thus establishing sources of continued funding for registry sustainability.

We applaud the Executive Board of the German Aortic Valve Registry for their foresight in the creation of such a registry and on this excellent first report of one-year outcomes. We look forward to participation with GARY in the international consortium and to working collaboratively to maximize the opportunities manifest here to eventuate in improved patient outcomes.

REFERENCES