

## **International Consortium of Vascular Registries (ICVR) Meeting Minutes**

Thursday, May 19, 2016 at Hamburg-Eppendorf University Medical Center, Hamburg, Germany

### **InVASC AAA Project** - Adam Beck, Kevin Mani, Sebastian Debus

An abstract of this retrospective review has been accepted for plenary presentation at the ESVS meeting this fall. Data were discussed, specifically that there are significant variations across countries for size of aneurysm at repair, and for rupture rate, and some of these variations correspond to national healthcare reimbursement models. Additional suggestions for analyses were made, including: further evaluation of healthcare reimbursement models and diameter of aneurysm at repair/mode of treatment; aneurysms >5.5cm and rate of ruptured aneurysm repair. A manuscript is nearly completed, and will be circulated to all authors once additional analyses are completed based on the suggestions made at this meeting. It was agreed to submit this manuscript to JAMA or Lancet, and will consider EJVES or JVS if not accepted.

### **InVASC Carotid Project** - Maarit Venermo, Nicolaj Eldrup, Gabor Menhei, Grace Wang, Randy DeMartino

An abstract of this retrospective review has been accepted for poster presentation at the ESVS meeting this fall. Data were discussed. Additional suggestions for analyses were made. A manuscript is nearly completed. It was agreed to submit this to Stroke, and if not successful, for simultaneous publication in the Journal of Vascular Surgery and the European Journal of Vascular and Endovascular Surgery.

After the publication of above projects, it was discussed to write an editorial on international variations in vascular surgery based on the ICVR initiative for EJVES/JVS.

### **InVASC Leg Bypass - PVI Project** – Christian Behrendt, Sebastian Debus, Danny Bertges, Birgitta Sigvant

The potential for a retrospective analysis among countries with existing registries was discussed, along with the needed core data elements needed. It was agreed that the investigators would define the minimum dataset, informed by the RAPID project and survey of existing registries, to determine which countries could contribute data later this year

### **ICVR Prospective AAA Project (IPAP)** – Kevin Mani, Adam Beck

This project was extensively discussed and it was decided to focus on initial and 2 year follow-up of EVAR treatment of elective and ruptured AAA in centers among all ICVR countries that agree to participate in a project to enter additional initial as well as follow-up data for all cases during a 1-2 year period, depending on how many centers agree to participate. The required data elements will be defined and each participating registry in ICVR will invite their members to participate. Kevin and Adam will distribute a core data set for consideration by the working group soon. Discussions will be held with international regulators and industry to determine if any funding could be made available to offset additional cost for data entry in participating centers. Once the core data set is established and funding is available, a request for participating centers will be distributed.

### **Future Projects Comparing Outcomes**

This concept was discussed and there was agreement that outcomes should be compared among identified countries as long as the accuracy of the outcomes can be validated beyond data entered into

the registry, such as by national mortality or claims data. Mortality is the outcome most easily validated across multiple registries. In-hospital or 30-day (whichever is longer) would be the ideal measure. To avoid the need for complex risk-adjustment, which might depend on clinical data variably recorded in registries, the concept of studying elective repair of small-medium sized AAA was considered the best initial project. In the case of such a prophylactic procedure, the patient risk must be evaluated before recommending repair, so that risk-adjustment is not appropriate. This type of analysis also accounts for optimal patient selection as well as outcome. The mortality after rupture AAA (EVAR vs open) was also discussed, and because of the high event rate, it was agreed that this could be a good first project with outcomes. It was agreed to perform an outcome analysis with new years of data, to span 2012-2015 when these data are available later this year. Initial project plan will be drafted by Nikolai Eldrup and Jacob Budtz-Lilly, Denmark.

#### **Device Surveillance using Claims Data**

The need for long-term surveillance of real world device effectiveness is widely recognized, and international collaboration would be valued by FDA and other national regulatory agencies. This was discussed and it is recognized that not all registries in ICVR can match their initial clinical data with subsequent national claims data. However, there is potential for several national registries in ICVR to collaborate on a future project in this area, which will be discussed in more detail at future meetings.

#### **Registry Assessment of Peripheral Interventional Devices (RAPID) Project**

This project to define the minimum core dataset necessary to create interoperable data extraction from multiple sources for device evaluation was discussed. In addition to VQI, the Australian and German registries provided data forms for inclusion in this project which has been done under MDEpiNet sponsorship at the Duke Clinical Research Institute. Approximately 100 variables unique to PVI evaluation have been selected from society registry forms and industry clinical research forms, and appropriate definitions and meta data assembled. These will be circulated when available for all to use, and serve as a potential basis for future collaborative projects across registries.

#### **Next Meeting**

It was agreed to hold the next ICVR meeting on Tue, November 15, 2016 in New York City, during the week of the Veith meeting. A location in the hotel will be explored vs the Cornell Club.

Respectively submitted,

Martin Bjorck, Jack Cronenwett, Art Sedrakyan, Co-Chairs ICVR