

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

Tuesday, November 15, 2016 at New York Hilton Midtown Hotel, New York City, USA

### **InVASC Carotid and Aortic Projects – Maarit Venermo, Adam Beck [slides attached]**

These projects presented at the ESVS Meeting in September were presented and discussed. The AAA paper was published recently in Circulation, and the carotid paper is under review by the JVS and EJVES.

Discussion: Add a data field to ICVR registries to understand why AAA < recommended threshold diameter is being electively repaired. New analysis focusing on threshold dia for repair, health economics and center case volume.

### **InVASC PAD Project – Christian Behrendt, Jack Cronenwett [slides attached]**

The initial results of the Delphi survey were presented along with the core data set created in the MDEpiNet RAPID project. The ICVR Delphi survey will be refined and merged with RAPID core data elements to develop recommendation for variables to be included in ICVR registries for future studies. A retrospective PAD project can be done comparing variation in PVI vs bypass and % claudicants vs CLI treatment by country, based on data which is now available in VQI and which should be available for Vascunet countries by mid-2017.

Discussion: The working group for InVASC PAD would be Christian Behrendt, Danny Bertges, Birgitta Sigvant, and Andy Schanzer. The value of incorporating patient reported outcomes for claudication treatment into ICVR registries, such as VascuQOL, was again discussed.

### **Potential New InVASC Projects – Kevin Mani, Adam Beck [slides attached]**

In a general discussion, it was agreed that ICVR countries are comfortable reporting outcomes, recognizing that initial projects should be focused on topics that have clear outcomes (e.g., mortality).

Comparing mortality of open and EVAR treatment of ruptured AAA across countries was discussed as a potential project using data from 2010-2016 to compare trends over time, including mortality, with a sub-study focused on outcomes in women. Mortality outcomes could be indexed in comparison with outcome of elective repair in centers. Jacob Budtz-Lilly is interested in this project which would need 2016 data available for Vascunet countries in mid-2017.

Comparing outcomes of acute (complicated vs. uncomplicated) and chronic descending aortic dissection treated by TEVAR was discussed as a potential new project. In addition, studying outcome of popliteal aneurysm treatment, or variation in treatment (open vs. endo) was suggested as a topic for future discussion.

The potential to compare outcomes that do not need risk adjustment was discussed. In cases of prophylactic treatment of small AAA, asymptomatic carotid, and claudication patients, the decision to recommend treatment implies an assessment of risk, such that risk adjustment for key outcomes is not needed. Also discussed was a potential project analyzing variation of interval between symptoms and treatment of carotid disease across countries.

### **Claims Data Linkages for Late Outcomes – Art Sedrakyan, Christian Behrendt [slides attached]**

The use of claims data for tracking late outcomes in the US VISION project and the German insurance claims evaluation project was presented. There appear to be 6 countries in ICVR with the potential to

match national claims data with registry data to perform a collaborative project in this area. The initial project could focus on late mortality which would be sufficient for several long term outcome projects.

**Vision for Prospective Studies in ICVR – Danica Marinac-Dabic, Martin Björck [slides attached]**

The new US National Evaluation System for Health Technology (NEST) was presented, which will promote increased opportunities for device evaluation in registries. Industry has a growing focus on post-market clinical follow-up; relaxing requirements to allow more use of registries internationally would benefit all parties. The International Medical Device Regulators Forum (IMDRF) will meet in Moscow on December 7-9 and ICVR will try to arrange a conference call with them to discuss potential ICVR interaction with IMDRF, with a goal to invite European regulators, such as Andy Crosby from UK to the spring meeting in Helsinki on May 17-18.

The TASTE RCT nested in Swedish PCI cardiology registries was discussed as a potential model for future prospective trials nested in ICVR registries. Oral informed consent was permitted for this project.

**IPAP Project: EVAR Treatment of Elective and Ruptured AAA – Adam Beck, Kevin Mani, Jack Cronenwett [slides attached]**

This project will recruit interested centers which agree to collect at least 2-year follow-up after EVAR for intact and ruptured AAA including device specific information, for all cases done during one year. There was recommendation to initially focus only on ruptured AAA, to decrease data entry burden, which will need to be decided. Not all countries will need to start at the same time, as some are ready now (Finland, Denmark, USA, Sweden, Hungary), and others will need to add some data elements (e.g., device details of key endpoint in follow-up) to their registry. Core data elements need final definition. The co-chairs for this project are Adam and Kevin, and it is hoped to start recruiting centers in early 2017. The potential need for imaging core lab review only for patients who required intervention was discussed. Industry has interest in label expansion to include ruptured AAA, which could provide a basis for funding if regulators agreed to consider such data.

**Potential Grant Funding – Art Sedrakyan**

Grant funding for ICVR projects was discussed. NIH and other agencies typically fund trials, which could be organized by ICVR, such as dual anti-platelet therapy after PVI, or high vs. low dose statin therapy. Other ideas could be rare vascular diseases. Conference grants are available from AHRQ and others, and industry foundation funding may be available. A small working group will be organized by Art to pursue this.

**Disseminating ICVR success and Next Steps**

ICVR will have special sessions at the SVS VAM on May 31 in San Diego, California and at the ESVS meeting on September 19-22, in Lyon, France. These will allow communication to members not familiar with ICVR and will highlight accomplishments to date. It was also suggested that ICVR pursue publications in Endovascular Today and updates on various websites, such as MDEpiNet.

**Next Meeting**

It was agreed to hold the next ICVR meeting on May 17-18, 2017 in Helsinki, Finland.

Respectfully submitted,

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