ICVR Nov 17, 2017 Meeting Summary

Attendees: Martin Altreuther, M.D., Nobuyoshi Azuma, M.D., Courtney Baird, M.S., Adam Beck, M.D., Christian-Alexander Behrendt, M.D., Daniel Bertges, M.D., FACS, Martin Björck, M.D., Roberta Bloss, Jon Boyle, M.D., Jack Cronenwett, M.D., Eike Sebastian Debus, M.D., Ph.D., Nikolaj Eldrup, M.D., Jens Eldrup-Jorgensen, M.D., Philip Goodney, M.D., M.S., Matthew Grima, M.D., MSc, Ted Heise, Ph.D., RAC, Cristina Isaia, Larry W. Kraiss, M.D., Kevin Mani, M.D., Jialin Mao, M.D., M.S., Danica Marinac-Dabic, M.D., Ph.D., Gabor Menyhei, M.D., Salvatore Scali, M.D., Marc Schermerhorn, M.D., Pablo Morales, M.D., Art Sedrakyan, M.D., Ph.D., Carlo Setacci, M.D., Nicla Settembre, M.D., Ph.D., Murray Sheldon, M.D., Matthew Thompson, M.D., Maarit Venermo, M.D., Jim Wadzinski, Grace Wang, M.D., Scott Williams, M.S., RAC

1. **Outcome of elective and ruptured AAA repair, open vs EVAR using 2010-2016 Vascunet + VQI data.** Project team: **Adam Beck, Kevin Mani**, Christian Behrendt, Marc Schermerhorn, Sal Scali, Jon Boyle. Two project ideas have been proposed 2010-2016 AAA data:
   1) Variation in AAA outcome for elective and ruptured AAA by country, including associated treatment, change over time, AAA size and patient characteristic analysis.
   2) Center volume and outcome study by aneurysm intact/rupture status and treatment, without comparison of country variation.
   Next steps: Finish collecting data from all countries, specify details of analysis for Cornell team, discuss participation with countries that cannot submit individual patient level data to incorporate aggregate level data. (including UK, Germany and Japan)
2. **Impact of center volume on outcome of CEA and CAS in symptomatic and asymptomatic patients using Vascunet + VQI data.** Project team: **Grace Wang**, **Maarit Venermo**, Gabor Menyhei, Martin Björck. Reviewed availability of outcome data in 2010-2013 Vascunet data. Next round of carotid data collection will be late 2018. Decided to use existing 2010-2013 data, not to compare country variation, but to evaluate center volume vs in-hosp (or 30-day, whichever registry contains) stroke and death rate after CEA (not enough data for CAS), and look at impact of factors such as anesthesia, shunt, patch, etc. on outcome.
   Next steps: There are data from France, Malta and Japan that may be able to be added plus aggregate data from Germany and UK. Obtain VQI data and determine methods for individual registries to validate their stroke and mortality rate (stroke may be validated by comparing with stroke/death ratio).
   The next data collection on carotid procedures will be on 2018. Delay between index symptoms and procedure will be one focus of the next analysis.
3. **Variation in transfusion threshold based on blood loss and Hb level.** Potential future RCT of transfusion threshold discussed by Nicolaj Eldrup. VQI has data on pre-op Hb, transfusion and EBL for open AAA which could be analyzed.
4. **Final results and pending publication of Delphi survey for PAD core data elements.** Summary presented, harmonized levels for co-variates accepted. Delphi manuscript being circulated for comments by Christian Behrendt.
5. **Variation in PAD treatment, bypass vs PVI for claudication vs CLI between and within ICVR countries.** Project team: **Christian Behrendt**, Danny Bertges, Birgitta Sigvant, Martin Björck. Focus on infrainguinal treatment looking at variation in indication for treatment and bypass vs intervention, with some additional details such as bypass conduit, target artery, intervention type.

Discussed whether data could be available before Vascunet planned extraction in 2019, group will explore which countries can do this.

Next steps: Develop a list of variables for a minimum dataset that can be collected within current registries and survey registries in terms of data availability and participation.

6. **Ideas for potential new projects involving existing data from some registries.**
    - **a.** TEVAR, analyze indication variation or focus on dissection practice and outcomes
    - **b.** Registry-nested RCT, medical vs TEVAR treatment of uncomplicated type B dissection
    - **c.** Ruptured thoracic aneurysm, size at rupture and how treated
    - **d.** Asymptomatic carotid treatment, which patients benefit, eg, survive long enough
    - **e.** Amputations (mortality and predictor of outcomes)
    - f. EVAR conversions/explant outcomes
    - g. Mycotic AAAs
    - h. Aorto-enteric fistulae
7. **New topics discussed.**
    - **a.** Potential to track rare diseases by ICVR countries. Peter Lawrence has established the Vascular Low Frequency Disease Consortium (http://surgery.ucla.edu/vlfdc) and invites participation from all countries.
    - **b.** New European General Data Protection Regulations (GDPR) were discussed, as this could impact future potential to share data between countries. The regulations will take effect in May 2018, but the details and impact remain to be determined. Discussed possible infrastructure to harbor data under the regulations.

Prospective Project: EVAR Device evaluation for Ruptured AAA. Project leads: **Kevin Mani, Adam Beck, Pablo Morales.** The goal of this project is to compare the in-hospital (or 30 day) mortality for open vs EVAR treatment of ruptured infra-renal AAA. Since EVAR devices were approved based on elective repair trials, there exist precaution statements in IFU indicating lack of date concerning rAAA. Removing these precautions or specifying rupture as an approved indication could benefit manufacturers by allowing them to train sites specifically for rupture or potentially reducing liability exposure (Matt Thompson), even though it may not extend market share. FDA representatives shared that a minimum number of procedures for each device type would be required, and based on power analysis, this is likely 100-150, although precise calculations are required. At least 6 ICVR registries have been collecting data during the past year that provides details of device main body and iliac limb types required for analysis. These patients could be included and combined with procedures from these and additional registries during 2018. Similar data from open treatment of rAAA could serve as a control arm with large n to reduce the n of EVAR procedures required. Must insure that all cases from participating centers are included. Consider retrospective data collection approach to enroll many patients or hybrid approach of collecting both retrospectively and prospectively. It will be important that multiple regulatory bodies, and not just FDA, agree to consider IFU expansion based on the details developed for this project.

Next Steps: Constitute a working group with members from each company that desires to participate and each regulatory body, plus ICVR members, to define the details of the project. Draft a brief protocol for IMDRF to review. Danica Marinac-Dabic will invite regulators involved in IMDRF so that the project will satisfy international regulators as well. Funding a small amount per patient would likely encourage center participation, and some MDEpiNet funding could be provided.

8. **New ideas for future device evaluation projects.**
    - **a.** Patch material used for endarterectomy
    - **b.** Branched/fenestrated thoracoabdominal grafts
    - **c.** A-I devices used for occlusive disease
    - d. Iliac venous stents
    - e. Thoracic arch grafts: left subclavian- fenestrated grafts
    - f. Explanted EVAR and TEVAR device analysis and outcome
9. **Next Meetings.**
    - a. Iceland 2018, May 30 – June 1. Combined with Vascunet meeting. Schedule within these days to be finalized after evaluating flight schedules from Europe and U.S.
    - b. NYC, Nov, 2018. A straw poll indicated that there was slight preference for Fri>Tue>Mon>Wed during the Veith meeting, to allow over weekend travel to reduce airfare for those only attending ICVR meeting. An email poll will be conducted to finalize this.