ICVR Delphi study and Variations in PAD treatment

15 NOV 2017 – NEW YORK CITY

BEHRENDT CA, BERTGES ES D
Aims and Scope

1st
To describe the International Consortium of Vascular Registries (ICVR) process for developing a minimal dataset for peripheral vascular intervention and open revascularization registries (ICVR Delphi study).

2nd
To compare international practice patterns for the revascularization of intermittent claudication and critical limb ischemia across several countries using the VQI and VASCUNET registries (international variations in PAD treatment).
Steps achieved since last meeting

• **ICVR Delphi study** manuscript drafted (email 13 Nov 2017)

• **VQI application** approved

  “This Project is an intriguing and innovative proposal and can be accomplished with the data in the VQI coupled with outside data.”

• **Request for available registry items** forwarded to all VASCUNET members (12 May 2017, 13 Nov 2017)
International Consortium of Vascular Registries Consensus

Recommendations for Peripheral Revascularization Registries

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ICVR Delphi study

Is There a Consensus on Consensus Methodology? Descriptions and Recommendations for Future Consensus Research

Panel composition

Panel size

Number of rounds

Rating

Limit of consensual agreement

Recommendation

Explain

At least 6 to 11

21 out of 31

At least 2 (ideal)

5 rounds

5-Point Likert-Scale

Depending on no. of items

80%

ICVR registry experts

5-Point Likert-Scale

“modified Delphi”
ICVR Delphi study

Invitation of international experts in vascular registry work
- 31 international experts have been invited
- 21 experts accepted and joined the panel

Collection of already established registry items
- Representatives of 14 national registries submitted their data dictionaries
- 171 registry items on peripheral arterial disease registries included into the panel discussion

First and second Delphi round
- 21 panel experts completed the first two Delphi rounds
- 171 items included into the first round

Not recommended
- 45 items "disagreed" or "strongly disagreed"

Recommended
- 78 items "agreed" or "strongly agreed"

Third and fourth Delphi round
- 19 panel experts completed the first four Delphi rounds
- 48 items included into the third round

Not recommended
- 14 items "disagreed" or "strongly disagreed"

Recommended
- 12 items "agreed" or "strongly agreed"

Final Delphi round No. 5
- 18 panel experts completed the final Delphi round
- 22 items included into the final round

Not recommended
- 16 items "disagreed" or "strongly disagreed"

Recommended
- 6 items have been recommended as Level-II

Final recommendation
- 90 items to be recommended as minimal dataset (Level-I)
- 6 items to be recommended as voluntary Level-II
ICVR Delphi study

Core variables
- Level I / II / III

ICVR Delphi study

Manuscript

Eldrup N - Core Risk Factors

Harmonize

90 plus 6 items

RAPID core data elements
## ICVR Delphi study

### Recommended items on logistics and infrastructure

<table>
<thead>
<tr>
<th>ITEM NAME</th>
<th>DEFINITION</th>
</tr>
</thead>
<tbody>
<tr>
<td>DATE OF ADMISSION</td>
<td>Day (dd), month (mm), and year (yyyy) of admission</td>
</tr>
<tr>
<td>MODE OF ADMISSION</td>
<td>Elective or emergent admission</td>
</tr>
<tr>
<td>DATE OF PROCEDURE</td>
<td>Day (dd), month (mm), and year (yyyy) of the procedure</td>
</tr>
<tr>
<td>DATE OF DISCHARGE</td>
<td>Day (dd), month (mm), and year (yyyy) of discharge</td>
</tr>
<tr>
<td>VOLUNTARY (LEVEL II):</td>
<td></td>
</tr>
<tr>
<td>DISCHARGE DESTINATION</td>
<td>e.g. discharged home, assisted living, rehabilitation facilities, nursery</td>
</tr>
</tbody>
</table>

### Recommended items on patient’s socio-demographics

<table>
<thead>
<tr>
<th>ITEM NAME</th>
<th>DEFINITION</th>
</tr>
</thead>
<tbody>
<tr>
<td>PATIENT’S AGE</td>
<td>Patient’s age in years</td>
</tr>
<tr>
<td>PATIENT’S GENDER</td>
<td>Male or female patient</td>
</tr>
<tr>
<td>FUNCTIONAL STATUS</td>
<td><strong>ECOG Performance Status, Developed by the Eastern Cooperative Oncology Group, Robert L. Comis, MD, Group Chair. Oken M, Creech R, Tormey D, et al. Toxicity and response criteria of the Eastern Cooperative Oncology Group. Am J Clin Oncol. 1982;5:649-655.</strong> A person's level of functioning in terms of their ability to care for them self, daily activity, and physical ability (walking, working etc.)</td>
</tr>
</tbody>
</table>
ICVR Delphi study

**Objectives:** A modified Delphi approach was conducted to achieve consensual agreement on a minimal dataset for peripheral arterial revascularization registries.

**Methods:** A modified Delphi questionnaire approach was used among vascular surgeons and international experts in registry work within the International Consortium of Vascular Registries (ICVR). Datasheets and item definitions of open and peripheral vascular intervention registries representing X countries were collected and subsequently analyzed to find variates to agree on.

**Results:** A total of 21 among 31 invited experts conducted five Delphi rounds. In total, 171 different items have been identified and included into the study. A total of 90 core items were recommended for a minimal dataset while 6 additional voluntary items could be identified. Data elements were broadly divided into logistical information, patient’s socio-demographics and risk factors, classification and assessment of the medical condition, best medical treatment, key procedural information including device specifications, procedure-related events and outcomes.

**Conclusions:** This large-scaled modified Delphi study with 21 international vascular registry experts could achieve a consensual agreement on a minimal dataset for registries on peripheral arterial disease. Further global harmonization of registry infrastructure and definition of items is needed to overcome limitations related to single-country investigations.
International Variations in PAD Treatment

When to start?

Which items/data types to compare?

Internal/external data validity

Analyses: data privacy
When to start

"annual topics"

AAA

2017

Carotid

2018

PAD

2019

Delphi study

Preparation

Data extraction

Analyses

1st Manuscript

Begin in 2018?
Which items and data types to compare?

Baseline **demographics** and **comorbidities**

**Rates of open** and **endovascular revascularizations for IC vs CLI**

**(Volume-Outcome-)** and **Reimbursement-Relationships**

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**Especially in PAD practice!**

- **External and internal validity**
- **National characteristics** (e.g., special disciplines performing procedures)
- **Primary registry data vs. Secondary claims data**
Which items and data types to compare?

- Different subsets of registries (variables)
- Application approved
- Common variable definition available
VASCUNET registries

Administrative
- Date of Admission
- Mode of Admission
- Date of Procedure
- Date of Discharge
- Voluntary: Discharge Dest.

Socio-dem.
- Patient’s Age
- Patient’s Gender
- Functional Status

General
- MOD. Rutherford Class.
- Existence of Ulcers
- Existence of Gangrene
- Existence of Rest Pain
- Existence of Infection
- Existence of AHI
- Voluntary: Fontaine-Class.
- Voluntary: WIFI-Class.

Internal validity, external validity

Primary registry data,
Secondary administrative (claims) data

Available/Not available,
Study time period
Data privacy (EU)

“Safe Harbor” 2015

“Privacy Shield”

EU-US

Inhomogeneous national legislation

Directive 95/46/EC of the European Parliament

2008/977/JHA Council Framework Decision

Transition phase

Reform of EU data protection rules

EU General Data Protection Regulation

May 2018

EU General Data Protection Regulation (EU-G DPR)

- Different federal/ regional regulations
- Different national regulations (in 28 EU countries)
- Directives and Decisions
  - “Privacy Shield”, Safe Harbor

European Union General Data Protection Regulation (EU-G DPR)

One for all
EU General Data Protection Regulation (EU-GDPR)

99 articles and 173 recitals

- Fine up to 20 million euros or 4% of global annual turnover

- Local data protection officer must be involved before and during processing of personal data on genetics and health

- Mandatory data protection impact assessment (potential harms and safeguards)

- Legal arrangements are necessary if data is transferred to countries that have not been approved by the EU authorities
The EU General Data Protection Regulation (GDPR) is the most important change in data privacy regulation in 20 years - we’re here to make sure you’re prepared.
Next steps

- Revise the ICVR Delphi study manuscript draft
- (your comments)
- Collect the response (VASCUNET)
- Interim report/Overview in Reykjavik (Iceland) 2018?
- Start the data comparison in 2018/2019?