What serious complications should vascular surgeons discuss with patients before a vascular intervention to reach truly informed consent?

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Disclosures

I do not have any (potential) conflict of interest

Background

- Informed consent & shared decision-making
- We usually discuss the ‘major’ complications
- But what is ‘major’?
- SVS Reporting Standards
  - To compare outcomes between published articles

Research question and methods

- Which complications after arterial vascular interventions do vascular surgeons consider to be ‘major’ or ‘minor’?
- E-Delphi method
  - Rounds of anonymous questionnaires
  - AAA, PAD, CAS
  - Vascular surgeons across USA and Europe

Methods

- 30-day and long-term complications (up to 30)
  - Cochrane reviews (AAA & CAS) and Dutch guideline (PAD)
- Three levels of severity (SVS):
  - Digital questionnaires (SurveyMonkey)

Results

- 46 experts responded:

<table>
<thead>
<tr>
<th>Vascular disease</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Abdominal Aortic Aneurysm</td>
<td>35 out of 78 (45%)</td>
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<tr>
<td>Carotid Artery Stenosis</td>
<td>26 out of 73 (36%)</td>
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<tr>
<td>Femoral Artery Disease</td>
<td>26 out of 66 (40%)</td>
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<tr>
<td>Total</td>
<td>129 out of 268 (48%)</td>
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</tbody>
</table>

- Consensus:

Consensus if >80% answered 1 or 2 → minor, 4 or 5 → major
Results

- **Major** complications after EVAR or open AAA repair (n=12):

1. Acute myocardial infarction requiring percutaneous coronary intervention or resuscitation
2. Stroke with permanent disability but ability to walk without support or loss of independency
3. Allergic reaction (due to contrast allergy) requiring to abort treatment and ventilation support
4. Aneurysm rupture requiring endovascular surgical re-intervention or open surgical repair
5. Renal failure requiring temporary dialysis with permanently reduced renal function requiring surveillance by a nephrologist or permanent dialysis
6. Thrombo-embolic event requiring below-ankle amputation, lytic therapy or fem-fem crossover surgery
7. Vascular graft infection controlled with antibiotics or requiring graft removal with in situ repair
8. Vascular graft deployment problem requiring conversion to open surgery or causing permanent disability and loss of independency
9. Bowel lesion requiring primary closure or anastomosis or a colostomy
10. Congestive heart failure requiring permanent medication or resuscitation
11. Pulmonary embolism requiring anticoagulant therapy or surgical therapy due to hemodynamic instability
12. Spinal cord ischemia regaining the ability to walk without support within 1 month or permanent paraplegia

Conclusion

- Consensus reached about major complications in common vascular surgical disorders

- Recommendation: discuss at least these major complications
  - More uniformity when informing patients
  - True informed consent
  - Facilitates shared decision-making

Major complications AAA, CAS, and PAD:

- Re-intervention in OR of intervention room
- Monitoring on MCU or ICU
- Spinal cord ischemia
- Infected prosthesis