New and emerging angioplasty technologies in development for severe lower limb ischaemia

June 2016
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The NIHR Horizon Scanning Research and Intelligence Centre (HSRIC) conducted this horizon scanning scoping review on behalf of the Birmingham Clinical Trials Unit (BCTU) BASIL-3 clinical trial team. The aim of the review was to identify new and emerging angioplasty-related technologies for arterial revascularisation in patients with severe lower limb ischaemia due to femoro-popliteal artery disease.

Peripheral artery disease (PAD) is a condition in which the peripheral arteries of the body, particularly those in the legs, are narrowed or blocked by a build-up of fatty deposits (atheroma). The most common initial symptom of lower limb PAD is leg pain, usually in the calf, while walking (intermittent claudication). In most people with intermittent claudication, the symptoms remain stable, however approximately 10-20% of people develop increasingly severe symptoms and 5-10% develop severe limb ischaemia. Severe or critical limb ischaemia is a seriously disabling, life and limb threatening, condition. It is characterised by severely diminished circulation, ischaemic pain at rest and tissue loss (ulceration and/or gangrene).

We searched a wide range of sources to identify new and emerging technologies including horizon scanning databases, commercial medical technology databases, clinical trial registries, research funding databases, industry news sources, bibliographical databases and conference proceedings. Initial findings were filtered using pre-determined inclusion and exclusion criteria leaving a list of new and emerging angioplasty-related technologies.

We identified thirty-one new and emerging technologies; 22 thought to be emerging and 9 that we believed to have been CE marked since 2015. We grouped the identified technologies by technology type e.g. drug-coated balloons, drug-eluting balloons, drug-eluting stents, stents with bio-active coating, self-expanding bare-metal stents, balloon-expandable bare-metal stents, covered stents, and spiral flow stents. We logged links to clinical trials and other key sources and provided the report to the BASIL-3 trial team for their trial group to discuss if there should be any adjustments to the trial protocol to accommodate these new and emerging technologies.
1 INTRODUCTION

Basil-3 is a multi-centre randomised controlled trial of clinical and cost-effectiveness of drug coated balloons, drug eluting stents and plain balloon angioplasty with bail-out bare metal stent revascularisation strategies for severe limb ischaemia due to femoro-popliteal disease that is being undertaken at the Birmingham Clinical Trials Unit. In response to a request from the BASIL-3 trial team, the NIHR Horizon Scanning Research and Intelligence Centre (HSRIC) undertook a horizon scanning scoping review to identify new and emerging angioplasty technologies in development for revascularisation in patients with severe lower limb ischaemia due to femoro-popliteal artery disease. The BASIL-3 trial team need to keep abreast of emergent technologies in this field in order to consider possible upstream amendments to the BASIL-3 trial protocol.

2 BACKGROUND

Peripheral arterial disease (PAD) is occlusive disease in which the peripheral arteries of the body, particularly those in the legs, are narrowed or blocked by a build-up of fatty deposits (atheroma). The most common initial symptom of lower limb PAD is leg pain, usually in the calf, while walking (intermittent claudication).1 In most people with intermittent claudication, the symptoms remain stable, however approximately 10-20% of people develop increasingly severe symptoms and 5-10% develop severe limb ischaemia.2 Severe or critical limb ischaemia is a serious, disabling, life and limb threatening, condition. It is characterised by severely diminished circulation, ischaemic pain at rest and tissue loss (ulceration and/or gangrene). The femoro-popliteal artery is the most common site of involvement in patients with atherosclerotic PAD.

2.1. MANAGEMENT OF SEVERE LIMB ISCHAEMIA

Aside from the management of pain, the main interventions for the management of severe limb ischaemia are revascularisation and amputation. Where revascularisation is required patients are currently offered angioplasty or bypass surgery, taking into account factors such as comorbidities, pattern of disease, availability of a vein, and patient preference.3

Current angioplasty techniques used for revascularisation of femoro-popliteal disease include:4,5

- Stents
  - Bare metal stents
  - Self-expanding stents
  - Drug-eluting stents
  - Covered self-expanding stents
- Balloon angioplasty
  - Plain balloon angioplasty
  - Drug-coated balloons

The NICE pathway for managing critical limb ischaemia in people with peripheral arterial disease states:3

- Patients should not be offered primary stent placement for critical limb ischaemia caused by aorto-iliac disease (except complete occlusion) or femoro-popliteal disease.
- Primary stent placement should be considered for critical limb ischaemia caused by complete aorto-iliac occlusion (rather than stenosis).
- Bare metal stents should be used when stenting is used for critical limb ischaemia.
- An autologous vein should be used whenever possible for patients with critical limb ischaemia having infra-inguinal bypass surgery.
• Percutaneous laser atherectomy may be used as an adjunct to recanalisation using balloon angioplasty. A stent may then be inserted to treat any stenosis and/or to prevent embolism and restenosis.

**RELATED NICE GUIDANCE**

• NICE clinical guideline. Peripheral arterial disease: diagnosis and management (CG147). August 2012. 6

• NICE interventional procedure guidance. Percutaneous laser atherectomy as an adjunct to balloon angioplasty (with or without stenting) for peripheral arterial disease (IPG433). November 2012. 7

3 **AIM**

The aim of the review is to identify new and emerging angioplasty technologies for arterial revascularisation in patients with severe lower limb ischaemia due to femoro-popliteal artery disease.

4 **METHODS**

4.1. **IDENTIFICATION**

We searched pre-specified sources to identify potentially relevant new and emerging technologies (see **appendix** for details). The sources included:

1. Horizon scanning databases
2. MedTech Industry news sites
3. Commercial medical technology databases.
4. Clinical trial registries and research funding databases
5. Industry news sites
6. Regulatory authorities/licensing bodies
7. Bibliographical databases
8. Appropriate company websites
9. Conference proceedings
10. Relevant professional bodies and charities
11. General internet search

4.2. **EXPERT INVOLVEMENT**

We contacted the BASIL-3 trial team for intelligence on relevant technology developments that they were already aware of.

4.3. **INVESTIGATION AND FILTRATION**

We undertook a brief investigation into each technology to identify technology type, drugs used, availability and CE marking, and links to key clinical trials. We removed duplicates when we had sufficient information to identify them and filtered the technologies using the agreed inclusion and exclusion criteria (Table 1).
Table 1: Agreed inclusion and exclusion criteria

<table>
<thead>
<tr>
<th>Key filtration points</th>
<th>Inclusion criteria</th>
<th>Exclusion criteria</th>
</tr>
</thead>
</table>
| Intervention type     | • Bare-metal stents.  
                        | • Drug-coated balloons and stents.  
                        | • Drug-eluting balloons and stents  
                        | used with endovascular surgery.     | • Vascular bypass devices/procedures.  
                        | • Re-canalisation, atherectomy and  
                        | endarterectomy devices/procedures.  
                        | • Technologies only in development for  
                        | cardiac revascularisation.          |
| Place in pathway      | • Revascularisation of femoro-  
                        | popliteal arteries in patients with  
                        | severe limb ischaemia.              | • Screening and prevention, intermittent  
                        |                                   | claudication or other symptoms of  
                        |                                   | peripheral arterial disease.        |
                        | • Tibial arterial disease only.    | |
| Stage in development  | • Emerging: novel technologies  
                        | being evaluated within a research  
                        | setting only – in phase I, II or III  
                        | clinical trials.                    | • Preclinical research.             |
                        | • New: novel technologies in the  
                        | process of being introduced into    | • Phase 0 and IV clinical research.  
                        | NHS use.                           | • Technologies already established for  
                        |                                   | clinical use in the NHS.            |
                        |                               | • No evidence of activity (e.g. updating) in  
                        |                                   | clinical trial registries in 2015 or 2016. |
| Study type            | • Interventional       | • <3 ‘single-case’ studies of the same  
                        | • ≥3 ‘single-case’ studies concerning  
                        | intervention.                      | Studies that are suspended, terminated,  
                        | the same intervention.             | withdrawn or status unknown.        |
|                      | Any                  | None.               |
| Research location/s   | Any                  | None.               |
| Developer type        | Any                  | None.               |

5 RESULTS

We identified 63 potentially relevant technologies from an initial 4,246 hits. Following a brief  
investigation, 32 technologies were excluded (Figure 1). Of the 31 technologies that met the  
inclusion criteria, 22 were deemed emerging i.e. still in clinical development and not CE marked  
(Tables 2 and 3) and nine were CE marked since January 2015 (Tables 2 and 4).
Figure 1: The number of technologies identified and excluded throughout the identification and filtration process.

- Identification
  - Potential technologies from initial search results (n = 4,246)
  - Non-relevant & duplicate results removed during identification (n = 4,183)

- Primary Filtration
  - Technologies (n = 63)
    - Technologies excluded based on inclusion/exclusion criteria (n = 20)

- Secondary Filtration
  - Technologies (n = 43)
    - Technologies excluded/ not relevant based on further information or duplicate (n = 12)

- Technologies included in the final report (n = 31)
  - New and/or emerging technologies (n = 22)
  - Recently CE marked (since Jan 2015) (n = 9)
Table 2: Sub-grouping of identified technologies

<table>
<thead>
<tr>
<th>Emerging technologies</th>
<th>Number</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Drug-coated balloons</td>
<td>7</td>
<td>3 paclitaxel</td>
</tr>
<tr>
<td></td>
<td></td>
<td>2 sirolimus</td>
</tr>
<tr>
<td></td>
<td></td>
<td>1 NF-kappaB decoy oligonucleotide</td>
</tr>
<tr>
<td></td>
<td></td>
<td>1 unknown</td>
</tr>
<tr>
<td>Drug-eluting balloons</td>
<td>3</td>
<td>2 paclitaxel</td>
</tr>
<tr>
<td></td>
<td></td>
<td>1 mitomycin</td>
</tr>
<tr>
<td>Drug-eluting stents</td>
<td>3</td>
<td>2 everolimus</td>
</tr>
<tr>
<td></td>
<td></td>
<td>1 paclitaxel</td>
</tr>
<tr>
<td></td>
<td></td>
<td>2 use a bio-absorbable scaffold</td>
</tr>
<tr>
<td>Stents with bio-active coating</td>
<td>1</td>
<td>Titanium-nitride-oxide bio-active coated stent</td>
</tr>
<tr>
<td>Self-expanding bare-metal stents</td>
<td>4</td>
<td></td>
</tr>
<tr>
<td>Balloon expandable bare-metal stents</td>
<td>1</td>
<td>In EU approval process</td>
</tr>
<tr>
<td>Covered stents</td>
<td>2</td>
<td>1 is CE marked</td>
</tr>
<tr>
<td></td>
<td></td>
<td>1 approved in USA; EU phase II clinical trials</td>
</tr>
<tr>
<td>Spiral flow stents</td>
<td>1</td>
<td>In pre-clinical testing</td>
</tr>
<tr>
<td>SUB-TOTAL</td>
<td>22</td>
<td></td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Technologies CE marked since 2015</th>
<th>Number</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Drug-coated balloons</td>
<td>3</td>
<td>All paclitaxel</td>
</tr>
<tr>
<td>Drug-eluting balloons</td>
<td>2</td>
<td>Both paclitaxel</td>
</tr>
<tr>
<td>Drug-coated stents</td>
<td>1</td>
<td>Paclitaxel coated self-expanding nitinol stent</td>
</tr>
<tr>
<td>Stents with bio-active coating</td>
<td>1</td>
<td>Titanium-nitride-oxide coated self-expanding nitinol stent</td>
</tr>
<tr>
<td>Self-expanding bare-metal stents</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td>SUB-TOTAL</td>
<td>9</td>
<td></td>
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</tbody>
</table>
Table 3: Emerging angioplasty technologies

<table>
<thead>
<tr>
<th>Technology</th>
<th>Technology type</th>
<th>Developer</th>
<th>Technology description</th>
<th>Development status</th>
<th>Clinical trial information</th>
<th>Links/further information</th>
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<tbody>
<tr>
<td><strong>Drug-coated balloons</strong></td>
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<tr>
<td>SeQuent® Please paclitaxel coated balloon catheter</td>
<td>Paclitaxel coated balloon</td>
<td>B. Braun Melsungen AG</td>
<td>Coronary balloon catheter for percutaneous transluminal coronary angioplasty. In clinical development for peripheral use. The balloon section is coated with paclitaxel at a dose of 3µg/mm². The balloon catheter is also coated in iopromide, an X-ray contrast medium which improves the solubility and transfer of paclitaxel to the vessel wall.</td>
<td>In phase III clinical trials for peripheral use. SeQuent Please is CE marked for primary coronary angioplasty with bare-metal stents and for restenosis.</td>
<td><a href="https://clinicaltrials.gov/ct2/show/NCT01970579">https://clinicaltrials.gov/ct2/show/NCT01970579</a></td>
<td><a href="http://www.deb-bbraun.com/">http://www.deb-bbraun.com/</a></td>
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<tr>
<td>Paclitaxel drug coated balloon - peripheral</td>
<td>Paclitaxel coated balloon</td>
<td>Vascular Nanotransfer Technologies</td>
<td>A nano-carrier based PTA peripheral drug coated balloon designed for controlled paclitaxel delivery at a lower dose and minimal dislodgement of the coating into the distal vessel.</td>
<td>Estimated approval: Jul 17 Estimated launch: Oct 17.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Drug Coated Balloon</td>
<td>Drug Manufacturer</td>
<td>Drug Technologies</td>
<td>Description</td>
<td>Development Stage</td>
<td>Notes</td>
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<tr>
<td><strong>Drug-eluting balloons</strong></td>
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</table>

<p>| <strong>Drug-eluting stents</strong> |  |  |  |  |  |  |
|--------------------------|-----------------|-----------------|-------------------------------------------------|--------------------------------------------------|
| <strong>Stanza™ Bioresorbable paclitaxel-eluting scaffold</strong> | Bioresorbable, paclitaxel-eluting, self-expanding scaffold | 480 Biomedical | Paclitaxel-eluting stent with a radial stiffness equal to metallic stents, flexible and conforms to the vessel, adapting to leg movement. Company claims that bioresorbability means no permanent implant is left behind to cause irritation or complications after the scaffold supported the vessel during the critical healing period. The Stanza™ scaffold resorbs in about one year. | The STANCE study. Clinical studies are ongoing, the SPRINT trial. | <a href="https://clinicaltrials.gov/ct2/show/NCT01403077?term=STANCE&amp;rank=6">https://clinicaltrials.gov/ct2/show/NCT01403077?term=STANCE&amp;rank=6</a> | <a href="http://www.480biomedical.com/products/stanza-bioresorbable-scaffold">http://www.480biomedical.com/products/stanza-bioresorbable-scaffold</a> |
| <strong>SPRINT</strong> | <a href="https://clinicaltrials.gov/ct2/show/NCT02097082?term=480+Biomedical&amp;rank=2">https://clinicaltrials.gov/ct2/show/NCT02097082?term=480+Biomedical&amp;rank=2</a> |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Stents with bio-active coating |  |  |  |  |  |  |  |
| HELIOS LD peripheral balloon expandable bio-active stent | Balloon expandable bio-active stent | Hexacath | A titanium nitride oxide bio-active coated peripheral vascular stent. The bio-active coating claims to reduce platelet and fibrin deposition, minimize corrosion and inflammation, promote re-endothelialisation and decrease thrombus formation. It is a flexible stent having dual-helix structure and is made up of Cobalt Chromium. It is a low profile device with low strut thickness and 6F sheath compatibility. | CE Mark ongoing. | <a href="https://clinicaltrials.gov/ct2/show/NCT01500070?term=NCT01500070&amp;rank=1">https://clinicaltrials.gov/ct2/show/NCT01500070?term=NCT01500070&amp;rank=1</a> | <a href="http://www.hexacath.com/helios-lld/">http://www.hexacath.com/helios-lld/</a> |  |
| Self-expanding bare-metal stents |  |  |  |  |  |  |  |
| iVolution peripheral stent | Self-expanding nitinol stent |  | Self-expanding nitinol stent design based on multiple undulating rings that extend axially without connection bridges forming an open-cell stent. The metal at the stent ends is less dense in artery coverage, and incorporates a series of radiopaque markers to visualise the stent once expanded. | In phase II/III clinical trials. | <a href="https://clinicaltrials.gov/ct2/show/NCT02430922?term=NCT02430922&amp;rank=1">https://clinicaltrials.gov/ct2/show/NCT02430922?term=NCT02430922&amp;rank=1</a> | <a href="http://www.ivascular.global/">http://www.ivascular.global/</a> |  |</p>
<table>
<thead>
<tr>
<th><strong>Pulsar-18 self Expanding stent</strong></th>
<th>Self-expanding bare metal stent</th>
<th>Biotronik SE &amp; Co. KG</th>
<th>Self-expanding stent with asymmetrical S-shape articulations and Peak-to-Valley design that claims to prevent fish-scaling and provide fatigue resistance through improved axial and bending flexibility. It has diameter of 4 to 7 mm and allows treatment of both superficial femoral artery and below-the-knee disease, with lengths from 20 to 200 mm.</th>
<th>Estimated approval: Feb 19. Estimated launch: May 19.</th>
<th><a href="http://www.dicardiology.com/product/fda-clears-peripheral-stent-biotronik">http://www.dicardiology.com/product/fda-clears-peripheral-stent-biotronik</a></th>
</tr>
</thead>
</table>

**Balloon-expandable bare-metal stents**

| euca PWS | Balloon expandable stent system | eucatech | eucaPWS has a nine crown design for optimal lumen coverage and adaption to the vessel wall. The stent has a smooth hemodynamic surface with rounded edges to reduce vessel irritation. Open cell structure for easy side branch access. Open cell design with coaxial connected interlinks for optimal flexibility. | In EU approval process. | [http://www.eucatech.de/en/produkte/radiologie/stents/eucapWS.php](http://www.eucatech.de/en/produkte/radiologie/stents/eucapWS.php) |

**Covered stents**

| Prograft SX | Balloon expandable covered stent | Vascular Concepts | Prograft SX is a balloon expandable, covered, peripheral vascular stent. | CE Mark ongoing. | [http://wwwvascularconcepts.com/content/pages.php?pg=products_prograft](http://wwwvascularconcepts.com/content/pages.php?pg=products_prograft) |
|---|---|---|---|---|---|---|

**Spiral flow stents**

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</tbody>
</table>

[https://vascular-flow.com/](https://vascular-flow.com/)
### Table 4: Recently CE marked angioplasty technologies

<table>
<thead>
<tr>
<th>Technology</th>
<th>Technology type</th>
<th>Developer</th>
<th>Technology description</th>
<th>Development status</th>
<th>Clinical trial information</th>
<th>Further information</th>
</tr>
</thead>
<tbody>
<tr>
<td>Drug-eluting balloons</td>
<td>Paclitaxel-coated balloon catheter</td>
<td>Acotec Scientific Co., Ltd</td>
<td>Paclitaxel-coated percutaneous transluminal angioplasty (PTA) catheters orchid (0.035 inch), Tulip (0.018 inch), and Lotus (0.0.14 inch).</td>
<td>CE marked 2015.</td>
<td><a href="https://clinicaltrials.gov/ct2/show/NCT01850056?term=orchid+AND+balloon&amp;rank=1">https://clinicaltrials.gov/ct2/show/NCT01850056?term=orchid+AND+balloon&amp;rank=1</a></td>
<td><a href="http://www.acotec.org/">http://www.acotec.org/</a></td>
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<td>---------------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>D&amp;T (dilate and treat) PTA drug-delivery catheter</td>
<td>Drug eluting balloon catheter</td>
<td>Acrostak (Schweiz) AG (Winterthur, Switzerland)</td>
<td>D&amp;T (dilate and treat) PTA catheter delivers liquid paclitaxel or other agents to peripheral vascular lesions through small holes as balloon inflates.</td>
<td>CE Marked - date unknown. Available France.</td>
<td></td>
<td><a href="http://www.acrostak.com/index.php">http://www.acrostak.com/index.php</a></td>
</tr>
</tbody>
</table>
### Stents with bio-active coating

<table>
<thead>
<tr>
<th>Stent Name</th>
<th>Material and Coating</th>
<th>Indication</th>
<th>CE Mark</th>
<th>Website</th>
</tr>
</thead>
<tbody>
<tr>
<td>HELIFLEX Ti</td>
<td>Self-expanding nitinol stent</td>
<td>Titanium-nitride-oxide coated self-expanding nitinol stent indicated for use in patients with atherosclerotic disease of the lower limbs and for the treatment of sub-optimal results after percutaneous transluminal angioplasty such as artery recoil, residual stenosis, dissections, restenosis and/or occlusions.</td>
<td>CE Marked – date unknown, available.</td>
<td><a href="#">Link</a></td>
</tr>
<tr>
<td>Hexacath</td>
<td>Self-expanding nitinol stent</td>
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### Self-expanding bare-metal stents

<table>
<thead>
<tr>
<th>Stent Name</th>
<th>Material and Coating</th>
<th>Indication</th>
<th>CE Mark</th>
<th>Website</th>
</tr>
</thead>
<tbody>
<tr>
<td>Protégé GPS</td>
<td>Self-expanding peripheral stent system</td>
<td>Self-expanding Nitinol stent system. The stent comes on a 6F over-the-wire delivery system. The stent has an open lattice design and tantalum radiopaque markers at the proximal and distal ends.</td>
<td>CE marked FDA approved Jan 2015. <a href="#">Link</a></td>
<td><a href="#">Link</a></td>
</tr>
<tr>
<td>Medtronic; Covidien</td>
<td>Self-expanding stent</td>
<td></td>
<td><a href="http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalandClearances/Recently-ApprovedDevices/ucm431348.htm">http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalandClearances/Recently-ApprovedDevices/ucm431348.htm</a></td>
<td></td>
</tr>
</tbody>
</table>

[Link](https://clinicaltrials.gov/ct2/show/NCT00530712?term=NCT00530712&rank=1)
### Horizon scanning databases
- NIHR HSRIC ‘in-house’ technology database
- ECRI Institute [http://www.ecri.org](http://www.ecri.org)
- EuroScan [www.euroscan.org](http://www.euroscan.org)
- CADTH [https://www.cadth.ca](https://www.cadth.ca)

### MedTech industry news sites
- Clinica MedTech [http://www.clinica.co.uk/](http://www.clinica.co.uk/)
- Fierce Network – Fierce Diagnostics: [http://www.fiercediagnostics.com](http://www.fiercediagnostics.com)

### Commercial technology databases

### Clinical trial registries
- WHO International Clinical Trials registry platform (ICRTP) [http://apps.who.int/trialsearch/AdvSearch.aspx](http://apps.who.int/trialsearch/AdvSearch.aspx)

### Regulatory authorities/Licensing bodies

### Bibliographic databases
- Ovid MEDLINE® In-process & Other Non-indexed Citations (to current date)

### General internet
- Google [https://www.google.co.uk/](https://www.google.co.uk/)

### Scientific conference proceedings

### Charity websites
- British Heart Foundation [https://www.bhf.org.uk/](https://www.bhf.org.uk/)
- American Heart Association [http://www.heart.org/](http://www.heart.org/)

### Professional bodies websites
- Royal College of Surgeons [https://www.rcseng.ac.uk/media/media-background-briefings-and-statistics/the-surgical-specialties-10-vascular-surgery](https://www.rcseng.ac.uk/media/media-background-briefings-and-statistics/the-surgical-specialties-10-vascular-surgery)
- The Royal College of Radiologists [https://www.rcr.ac.uk/](https://www.rcr.ac.uk/)
7 REFERENCES


