# National Institute for Health and Clinical Excellence

## 816/1 – Percutaneous atherectomy of femoropopliteal arterial lesions with plaque excision devices

### Consultation Comments table

### IPAC date: Thursday 9th December 2010

| Com. no. | Consultee name and organisation | Sec. no. | Comments | Response<br>Please respond to all comments |
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| 1 | Consultee 1<br>Secretary, vascular Society of Great Britain and Ireland | **1** | Agree with this | Thank you for your comment. Consultee agrees with guidance. |
| 2 | Consultee 2<br>NHS Professional | **1** | Plaque excision devices are also used in the management of fem-pop in-stent re-stenosis for the removal of intimal hyperplastic tissue.The indications for treatment and expected outcomes of plaque excision/atherectomy of primary atheromatous disease and in stent restenosis are different and a single recommendation covering both areas may be confusing. | Thank you for your comment. The scope for this procedure was not specific to primary atheromatous disease and the data available included case series with mixed indications including restenosis and, specifically, in-stent restenosis. |
| 3 | Consultee 1<br>Secretary, vascular Society of Great Britain and Ireland | **2.1** | Agree with this, but the specific atheromatous lesions suitable for atherectomy need to be more clearly defined. Clearly atherectomy is not indicated where simple balloon angioplasty and/or stenting would suffice. | Thank you for your comment. Consultee agrees with guidance. Section 1.3 of the guidance highlights that further research should define patient selection |
| 4 | Consultee 2<br>NHS Professional | **2.1** | Some patients with in stent restenosis will be asymptomatic with restenosis detected on stent surveillance. The indications for intervention are to preserve stent patency in some cases for long enough to achieve healing of ulcers and limb salvage. | Thank you for your comment. |

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| 5 | Consultee 1<br>Secretary, vascular Society of Great Britain and Ireland | **2.2** | Agree | Thank you for your comment. Consultee agrees with guidance. |
| 6 | Consultee 3<br>specialist advisor to NICE on this subject matter, on behalf of the British Society of Interventional Radiology | **2.2** | Atherectomy systems, in addition to being used as a stand-alone treatment option may also be used as an adjunctive therapy to facilitate more definitive procedures, not only stents but increasingly drug eluting balloons (the rationale being that the antiproliferative drug can penetrate the relevant layers of the arterial wall once the heavy burden of atheroma has been exised by atherectomy). | Thank you for your comment. Section 2.2.2 of the guidance has been changed to reflect use of drug eluting balloons. |
| 7 | Consultee 1<br>Secretary, vascular Society of Great Britain and Ireland | **2.3** | The outcomes of endovascular intervention are usually predicated more on the severity of the underlying disease, than the method used to treat it. Atherectomy has more to offer patients with more advanced disease, where plaque would otherwise not be controlled by balloon angioiplasty alone, and/or stenting. | Thank you for your comment. We recognise that the evidence contains mixed populations. The efficacy outcomes reported are those which are described in the available evidence. Table 2 of the overview contains more details about disease severity of the patients included in each study. |
| 8 | Consultee 2<br>NHS Professional | **2.3** | Data on the efficacy for the treatment of in-stent stenosis is also lacking with no randomised studies. Single centre cohort studies have generated conflicting data. Zeller et al J AM Coll Cardiol 2006.48.1573 | Thank you for your comment. We recognise that the evidence contains mixed populations The efficacy outcomes reported are those which are described in the available evidence. Zeller (2006) was included in Table 2 of the overview which contains more details about the indications of the patients included in each study. |

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| 9 | Consultee 3<br>specialist advisor to NICE on this subject matter, on behalf of the British Society of Interventional Radiology | **2.4** | 1. I think there is evidence of a learning curve with these devices that may impact on the adverse event rate (and thus the safety profile of the procedure)and that I would suggest specialist clinical support is available from industry for teams first using these devices 2. The use of distal embolic protection devices (that generally also have learning curves issues) may reduce the rate of distal embolisation | 1) Thank you for your comment. Specialist Advisers had a variety of opinions regarding training.<br><br>2) The safety outcomes reported are those which are described in the available evidence, it is not always clear whether embolic protection had been used Section 2.2.2 of the guidance states that a distal embolic protection device is sometimes used. |
| 10 | Consultee 1<br>Secretary, vascular Society of Great Britain and Ireland | **2.4** | The risk of distal embolisation with atherectomy seems higher than angioplasty and/or stenting, so the consent process should be explicit in this regard. There may also be training issues. Complex interventions are often more technically challenging, and require specific training. | Thank you for your comment. No controlled data are available for this procedure at present. |
| 11 | Consultee 4<br>NHS Professional | | I would like to commend the authors for an excellent comprehensive review of the available literature regarding the use of atherectomy in the treatment of patients with peripheral vascular disease. This was an unbiased review and summary of the available data. I would like to add to this review two more of my recently accepted and published abstracts pertaining to the distinct advantage for the use of atherectomy in the management of complex patients with limb threatening peripheral arterial disease. The authors also raise the question of the potential for embolization while performing the Silverhawk atherectomy procedure. We have several publications that directly address that issue also that I will include. | Thank you for your comment. Consultee agrees with guidance.<br><br>The consultee refers to a 2non peer-reviewed studies. The NICE IP Methods Guide highlights that efficacy outcomes from non peer-reviewed studies are not normally presented to the Committee.<br><br>The safety outcomes reported are those which are described in the available evidence, it is not always clear whether embolic protection had been used Section 2.2.2 of the guidance states that a distal embolic protection device is sometimes used. |

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| 12 | Consultee 4<br>NHS Professional | | The first abstract presented at Transcatheter Cardiovascular Therapeutics Conference (TCT) 2010 demonstrates the statistically significant advantage of treating patients who are at the highest risk of major amputation (Diabetics with critical limb ischemia) with directional atherectomy rather than balloon angioplasty with bailout stenting. This advantage in limb salvage as well as secondary patency is carried out to 30 months. This advantage has a dramatic impact on the quality of life of patients with the avoidance of amputation. | The consultee refers to a non peer-reviewed study. The NICE IP Methods Guide highlights that efficacy outcomes from non peer-reviewed studies are not normally presented to the Committee. |
| 13 | Consultee 4<br>NHS Professional | | The second published abstract recently presented at the MidWestern Vascular society meeting in Indianapolis, Indiana 2010 showed that African Americans generally present with the most advanced form of peripheral arterial disease (Critical Limb Ischemia) and have a significantly improved patency and limb salvage when treated with directional atherectomy rather than angioplasty or angioplasty with bailout stenting. There was also an advantage of atherectomy over PTA in Caucasians and Hispanics. | The consultee refers to a non peer-reviewed study. The NICE IP Methods Guide highlights that efficacy outcomes from non peer-reviewed studies are not normally presented to the Committee. |
| 14 | Consultee 4<br>NHS Professional | | Atherectomy has shown to have a distinct advantage in the management of the worse case patients with peripheral arterial disease and should be considered not only in these patients, but in all patients with peripheral arterial disease resulting in limb threatening ischemia or claudication (pain with ambulation in the calves). Interim data presented at the 2010 VIVA Conference Late Breaking Trials Session supports this hypothesis. | Thank you for your comment. Section 1.3 of the guidance recommends that further research should define patient selection. |

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| 15 | Consultee 4<br>NHS Professional | | The multispecialty, global DEFINITIVE LE study when complete, will be the largest P.A.D. device study to date with 800 subjects enrolled. Baseline patient demographics from DEFINITIVE LE indicate a challenging, real-world patient population. The study includes subset analysis for plaque morphology, lesion length, vessel plaque burden and the impact of diabetes. The robust study design includes independent, clinical event adjudication as well as core lab-verified angiographic and duplex data. Early results are favorable for atherectomy and indicate that atherectomy is effective in the treatment of heterogeneous real-world population and are also encouraging when comparing the outcomes of diabetics vs. non-diabetics. | Thank you for your comment. This study is not yet published. Details of this ongoing study will be added to the overview. |
| 16 | Consultee 4<br>NHS Professional | | In regards to the potential of distal embolization during an atherectomy we have extensively evaluated this potential and recently presented our data in a published abstract at the Eastern Vascular Society meeting in New York City October/2010. In this series reported by Dr Shrikhande the angiograms of 736 SilverHawk procedures were independently reviewed and the incidence of distal embolization was noted to be 1.9% with the majority of these occurring in patients with acute on chronic total occulsions. This incidence was slightly higer than the reportedembolization rate of 1.5 % in my Annals of vascular surgery paper quoted in your article but still very low. | Thank you for your comment. The consultee refers to a non peer-reviewed study. Safety outcomes regarding distal embolisation from the published literature are included in included in section 2.4.1 of the guidance. |