National Institute for Health and Clinical Excellence

386/2 – Endovascular stent insertion for intracranial atherosclerotic disease

Consultation Comments table

IPAC date: Thursday 10th May

Com. no.	Consultee name and organisation	Sec. no.	Comments	Response Please respond to all comments
1	Consultee 1 Specialist Adviser	**1**	Agree	Thank you for your comment.
2	Consultee 2 NHS Professional Royal College of Physicians	**1**	The RCP is grateful for the opportunity to respond to this consultation. Our experts believe that this represents a fair reflection of the available evidence. However, there are (very) occasional patients who have progressive/recurrent symptoms referable to an intracranial stenosis despite maximal medical therapy where the intervention may be used as a last resort to prevent major territorial infarction. These were not the type of patients recruited to the trials and it would be helpful if NICE acknowledged that there are few if any data about this particular group.	Thank you for your comment. The Committee considered this comment but decided not to change the guidance.

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3	Consultee 3 Johnson and Johnson Medical Manufacturer	**1**	At this current time, we don't disagree with NICE's current guidance that endovascular stents should only be used in the context of research. However NICE should be prepared to review this guidance when data from the two following ongoing studies becomes available: • VIST (Vertebral artery Ischaemia Stenting Trial) is an ongoing multi-centre, randomised controlled, open prospective clinical trial which compares vertebral artery stenting with best medical therapy. Â Prospective trial participants are chosen because they have had a recent stroke (within the last 6 months) and also have vertebral stenosis (50%). Data will become available for analysis in early 2013 • VISSIT (Vitesse Intracranial Stent Study for Ischemic Therapy) Trial) is a multicenter, randomized clinical trial to prospectively evaluate the safety, probable benefit, and effectiveness of the PHAROS Vitesse Neurovascular Stent System as well as evaluating the impact of stenting in the neurovasculature to treat cerebral ischemia on other outcomes such as hospital length of stay, charges, and costs. Data will become ready for analysis in early 2013. • The early experience of one centre in Massachusetts, USA that has enrolled five patients to date in the VISSIT is encouraging. They found that following stenting, CTP showed completely restored blood flow to the pre-existing hypoperfused territories and the 30 day mRS score was stable or improved after stenting in 3/4 patients. They therefore concluded that the treatment of symptomatic, high grade intracranial stenosis with the Pharos Vitesse stent is a safe procedure that has resulted in no permanent procedure related complications. (1) *(1) P-022 Treating symptomatic intracranial atherosclerosis with the balloon expandable Pharos Vitesse neurovascular stent: initial experience A Wakhloo1, N Patel1, A Thors1, E Duhamel1, J Morris2, M Ramzan2, M Moonis2, M Gounis1. NeuroIntervent Surg 20102:A25 doi:10.1136/jnis.2010.003236.22	Thank you for your comment. The IP Process Guide states that procedures with 'research only' guidance may be reassessed when relevant research is published. Suggestions for review of guidance from any source will be considered when there is new information that calls into question the validity of the current guidance. NICE would like to be informed of new and significant evidence that might prompt reconsideration of a procedure. The cited reference (Wakhloo A et al, 2010) was identified in the literature search but was not included in the overview because it is a conference abstract and does not mention any new safety outcomes.

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4	Consultee 4 NHS Professional	**1**	Given the recent early stopping of the RCT of stenting v medical theapy, SAMPRIS, due to a clear excess of adverse events in the stent group, and a lot of evidence pointing to high levels of risk factor exposure as the major cause of ICS, which much better medical management might help reduce, I think the NICE recommendation is about the only thing they could say on stenting at this time – only to be used in context of research.	Thank you for your comment.
5	Consultee 1 Specialist Adviser	**2.1**	Agree	Thank you for your comment.
6	Consultee 1 Specialist Adviser	**2.2**	Agree	Thank you for your comment.
7	Consultee 1 Specialist Adviser	**2.3**	Agree	Thank you for your comment.
8	Consultee 3 Johnson and Johnson Medical Manufacturer	**2.3**	We would like to highlight a study by Broussalis et al, (1) which concludes that VA origin stenting with the Pharos stent device is an effective treatment of stenosis. They recommend that the good clinical results compared to the high restenosis rates have to be examined in further studies. In particular, they suggest that ithas to be determined whether the Pharos stent allows the vessel time for collateralization, whether double antiplatelet treatment prevents recurrent cerebrovascular events or whether merely the low restenosis degree is causative for the clinical outcome (1) Treatment of vertebral artery origin stenosis with a Pharos stent device: a single center experience. Broussalis E, Kunz AB, Luthringshausen G, Klein S, McCoy MR, Trinka E, Killer-Oberpfalzer M. Interv Neuroradiol. 2011 Sep17(3):316-22. Epub 2011 Oct 17.	Thank you for your comment. The cited reference was identified in the updated literature search and will be added to appendix A of the overview.
9	Consultee 1 Specialist Adviser	**2.4**	Agree	Thank you for your comment.
10	Consultee 1 Specialist Adviser	**2.5**	Agree	Thank you for your comment.

"Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees."