

National Institute for Health and Care Excellence

IP 1317 – Transcervical extracorporeal reverse flow neuroprotection for reducing the risk of stroke during carotid artery stenting Consultation Comments table

IPAC date: Thursday 14th April 2016

Com. no.	Consultee name and organisation	Sec. no.	Comments	Response Please respond to all comments
1	Consultee 1 Professional Organisation Royal College of Physicians		Dear all The RCP is grateful for the opportunity to respond to the above consultation. Please see our response attached. I would be grateful if you could confirm receipt.	Thank you for your comment.
2	Consultee 1 Professional Organisation Royal College of Physicians		Re: Transcervical extracorporeal reverse flow neuroprotection for reducing the risk of stroke during carotid artery stenting: Interventional procedure consultation The Royal College of Physicians (RCP) plays a leading role in the delivery of high quality patient care by setting standards of medical practice and promoting clinical excellence. We provide physicians in the United Kingdom and overseas with education, training and support throughout their careers. As an independent body representing over 32,000 Fellows and Members worldwide, we advise and work with government, the public, patients and other professions to improve health and healthcare.	Thank you for your comment.

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3	Consultee 1 Professional Organisation Royal College of Physicians	General	The RCP is grateful for the opportunity to respond to the above consultation. We have liaised with The Joint Speciality Committee for Stroke Medicine and would like to make the following comments.	Thank you for your comment.
4	Consultee 1 Professional Organisation Royal College of Physicians	General	There is considerable concern about the quality of the studies that have been reviewed.	Thank you for your comment. The studies that are included in the overview either in the main extraction table (Table 2) or in Appendix A are the studies that were identified by a literature search on transcervical extracorporeal reverse flow neuroprotection for reducing the risk of stroke during carotid artery stenting.
5	Consultee 1 Professional Organisation Royal College of Physicians	General	There seems to have been an initial presumption that cerebral protection devices are beneficial, which may not be true, so that the comparisons were with other types of protection device rather than stenting without a protection device (or carotid surgery).	Thank you for your comment. The studies that are included in the overview either in the main extraction table (Table 2) or in Appendix A are the studies that were identified by a literature search on transcervical extracorporeal reverse flow neuroprotection for reducing the risk of stroke during carotid artery stenting. The IP programme does not assess the efficacy and safety of comparator interventions. The committee considered your comment and decided to add section 6.2 to the guidance as follows: “The committee was advised that the evidence for the clinical benefits of cerebral protection devices was not conclusive.”

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6	Consultee 1 Professional Organisation Royal College of Physicians	General	The below article from the ICSS trial should be considered by the panel to put the issues into perspective Doing D, Turner EL, Jobson J et al. Predictors of Stroke, Myocardial Infarction or Death within 30 Days of Carotid Artery Stenting: Results from the International Carotid Stenting Study. Eur J Vasc Endovasc Surg (2016); 51: 327-334. Yours faithfully Dr [REDACTED] [REDACTED]	Thank you for your comment. The IP programme does not assess the efficacy and safety of comparator interventions. The aim of the Doig (2016) paper was to determine if there were specific factors related to carotid artery stenting (CAS) procedures, process of care, or baseline patient characteristics that significantly increased or decreased the risk of stroke, myocardial infarction, or death within 30 days of CAS in the International Carotid Stenting Study (ICSS) comparing carotid artery stenting with endarterectomy for stroke prevention in patients with recently symptomatic carotid artery stenosis. In this study, protection devices were used in 585 out of 824 CAS patients and flow reversal protection devices were used in 26 of these 585 patients but no further details such as the types of flow reversal neuroprotection were provided. Therefore, this paper could not be included in the overview. However, it was brought to the attention of the committee and they decided to add section 6.2 to the guidance as follows: “The committee was advised that the evidence for the clinical benefits of cerebral protection devices was not conclusive.”

"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."