National Institute for Health and Care Excellence

IP1567 Superior rectal artery embolisation for haemorrhoids

IPAC 14/06/18

Com. no.	Consultee name and organisation	Sec. no.	Comments	Response Please respond to all comments
1	Consultee 1 NHS professional	General	At [redacted] we think this is a novel concept that could offer patients a quick easy treatment for symptomatic haemorrhoids as a day case procedure. We have been awarded a £9000 grant from the research development committee to recruit patients along NICE's current guidelines. Having read the guidance on the NICE web page I believe the information is an accurate representation of our current understanding.	Thank you for your comment. Consultee agrees with main recommendation.
2	Consultee 2 Company Boston Scientific	1.1	We are pleased to see NICE is considering the review of the evidence available on superior rectal artery embolization for haemorrhoids. Although we acknowledge the limited amount of evidence for this procedure, having carefully read your â€œOverviewâ€ document and in particular the section about available clinical studies, we ask NICE to note that only 1 patient across all studies reported complications after the procedure (Vidal 2015). Given the considerable progress in the field of interventional radiology with endovascular embolization it may be possible to achieve the	Thank you for your comment. The single safety event of 'painful, oedematous, perianal reaction' is described in the safety summary of the overview. The committee considered the current evidence on the safety and efficacy of the procedure to be inadequate in quality and quantity (there were 84

			same level of arterial occlusion obtained with Elective Doppler-guided hemorrhoidal artery ligation (DG-HAL), by placing coils in the branches of the superior rectal arteries. This endovascular embolization has the advantage of identifying all haemorrhoidal arterial branches, making it possible to completely occlude them with certainty, which could noticeably improve the therapeutic results. In addition, the vascular approach avoids all anal and rectal traumas which are inevitable with surgical treatment, even if they are minimally invasive; a reduction in morbidity following treatment is thus one of the improvements demonstrated (Vidal V et al. 2015). The safety of the procedure has been currently proved by 4 published studies.	patients from 3 case series). There is now an additional published case series of 25 patients.
3	Consultee 2 Company Boston Scientific	**1.2**	Community-based studies in the UK reported that haemorrhoids affect 13-36% of the general population (Haemorrhoids; NICE CKS, July 2016). Different therapeutic treatments of haemorrhoids exist depending on degree and severity of symptoms. Surgical treatment is necessary in 10% of cases (Madoff RD, et al. 2004) as indicated for high-graded haemorrhoids, or when non-operative approaches have failed, or complications have occurred. However, despite advances in office-based procedures and better surgical approaches, post-procedural pain and disease recurrence remain the most challenging problems in the surgical treatment of haemorrhoids, affecting between the 6%-10% of surgically treated patients. Consequently, novel management of haemorrhoids may focus at first on how to minimize pain following surgical failure and how to prevent recurrent haemorrhoids when no other therapy solutions is available. We agree with the need for further research and we would ask NICE to consider the implementation of a registry to ensure patient clinical data collection on this procedure. Furthermore, we believe it is important to prioritize the data collection for patients in stage IV with recurrence and/or pain after surgery assessing clinical measures such as patientâ€™s quality of life before and after the procedure while promoting a strong collaboration between proctologists and interventional radiologist in the auditing/registry process.	Thank you for your comment. Section 1.2 of the guidance recommends that further research should report details of patient selection. The Committee considered this comment but decided not to change the guidance.

			Madoff RD, Fleshman JW. American, Gastroenterological Association technical review on the diagnosis and treatment of haemorrhoids. Gastroenterology 2004;126(5):1463â€”73.	
4	Consultee 2 Company Boston Scientific	**1**	We would like NICE to consider the importance of providing clear guidance on the target population for this procedure. We recognise the limited evidence available on targeted patientsâ€™ subgroups, in fact current studies look at patients with grades of the disease from I to IV. However, if we consider the current management opportunities of internal haemorrhoids by grade as presented by Lohsiriwat (2012), patients with grade IV who failed the surgical approach seem to be the patient group who could potentially benefit the most from the embolization procedure. A practical solution might be a recommendation from NICE to segment patients with grade IV as the first target population for data collection, particularly as part of registry data collection.	Thank you for your comment. Section 1.2 of the guidance recommends that further research should report details of patient selection. A committee comment has been added, noting the lack of evidence on patient selection.
5	Consultee 2 Company Boston Scientific	**3.1**	We would like to ask NICE to consider an additional study for this guidance: â€¢ â€œEmbolization of the Superior Rectal Arteries for Hemorrhoidal Disease: Prospective Results in 25 Patientsâ€ by Tradi Farouk et al. (final publication is expected shortly) https://www.jvir.org/article/S1051-0443(18)30804-2/pdf.	Thank you for your comment. The cited publication was discussed by the committee and has been added to the evidence in table 2 of the overview.

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