National Institute for Health and Care Excellence

IP1791transapical transcatheter mitral valve in ring implantation following failed mitral valve repair surgery

IPAC date: 8 July 2021

Com. no.	Consultee name and organisation	Sec. no.	Comments	Response Please respond to all comments
1	Consultee 1 Cardiothoracic Services Clinical Reference Group, NHS England	**1.1**	The recommendation that this procedure may be used with special arrangements for clinical governance, consent, and audit or research is appropriate, and is consistent with current practice in the NHS.	Thank you for your comments and agreeing with the recommendation.
2	Consultee 2 Chair of British Cardiovascular Society (BCS) Guidelines committee on behalf of BCS.	**1.2**	BCS strongly supports the concept of data audit for new procedures such as this. This procedure is not currently included in a NICOR dataset. We are not clear what mechanism or funding arrangements would be required for its inclusion in this dataset. The BCS would support the establishment of such an appropriately-funded, sustainable registry."	Thank you for your comments and agreeing with the recommendation in 1.1. NICE understands that currently data on these procedures that could inform research or IPAC decision-making are not formally collected by NICOR. Therefore, bullet point 3 in section 1.2 in the guidance about data submission to a registry has been amended.
3	Consultee 3 Society for Cardiothoracic Surgery	**1.2, 1.4**	"A key aspect the registry where activity and outcomes are recorded and dessiminated. At the moment this procedure is not recorded on any of the NICOR datasets. MDT/Heart Team discussion is critical. Published outcomes demonstrate variable outcomes and this should only be considered for inoperable or very high risk cases"	Thank you for your comments. Bullet point 3 in section 1.2 in the guidance has been amended. Section 1.4 in the guidance clearly states that *"Patient selection should be done by a multidisciplinary team which must include interventional cardiologists experienced in the*

				procedure, cardiac surgeons, an expert in cardiac imaging, and where appropriate, a cardiac anaesthetist and a specialist in medicine for older people. The multidisciplinary team should determine the risk level for each patient and the device most suitable for them."
4	Consultee 1 Cardiothoracic Services Clinical Reference Group, NHS England	**2.5** **1.4, 1.5**	For the procedure, it states 'the mitral valve is accessed surgically', but it does not specifically say that the procedure should be a joint procedure between experienced surgeons and structural cardiology interventionalists. Hence, less specific than for the MDT person requirements. It does say on page 3, 1.5, that clinical teams should have regular experience in TAVI procedures. However, for maximum patient safety, and to make sure a cardiac surgeon immediately available to treat complications (as required in page 4, 1.5) it would be advisable to consider the requirement of trained cardiac surgeons to be involved in the procedure itself.	Thank you for your comments. Section 2 of the guidance is intended to be a summary of the procedure. Details of MDT requirements are presented in 1.4. section as follows: *"Patient selection should be done by a multidisciplinary team which must include interventional cardiologists experienced in the procedure, cardiac surgeons, an expert in cardiac imaging, and where appropriate, a cardiac anaesthetist and a specialist in medicine for older people. The multidisciplinary team should determine the risk level for each patient and the device most suitable for them."* Section1.5 also clearly states who and where these procedures should be done. *"The procedure is technically challenging and should only be done in specialised centres, and only by clinician teams with special training and experience in complex endovascular cardiac interventions, including regular experience in transcatheter valve implantation procedures. Centres doing these procedures should have cardiac surgical support for emergency treatment of complications and subsequent patient care."*

5	Consultee 2 Chair of British Cardiovascular Society (BCS) Guidelines committee on behalf of BCS.	**1.4**	We support the selection of suitable cases through a multidisciplinary process. We would strongly recommend that all patients with mitral valve failure have their situation looked at, taking into account individual circumstances and patient views, by a properly constituted multidisciplinary team. This should include those experienced in the use of interventional techniques such as valve in ring, or valve in valve, implantation.	Thank you for your comments. Section 1.4 in the guidance clearly states that *"Patient selection should be done by a multidisciplinary team which must include interventional cardiologists experienced in the procedure, cardiac surgeons, an expert in cardiac imaging, and where appropriate, a cardiac anaesthetist and a specialist in medicine for older people. The multidisciplinary team should determine the risk level for each patient and the device most suitable for them."*
6	Consultee 2 Chair of British Cardiovascular Society (BCS) Guidelines committee on behalf of BCS.	**1.5**	BCS welcomes the document on the use of this technique. UK experience in this area is limited, but there are centres that have had some experience. BCS would strongly recommend discussing such cases with clinicians from one of these centres when cases that might be suitable are identified.	Thank you for your comments. Section 1.5 in the guidance clearly states that *"The procedure is technically challenging and should only be done in specialised centres, and only by clinician teams with special training and experience in complex endovascular cardiac interventions, including regular experience in transcatheter valve implantation procedures. Centres doing these procedures should have cardiac surgical support for emergency treatment of complications and subsequent patient care."*
7	Consultee 1 Cardiothoracic Services Clinical Reference Group, NHS England	**3.4, 3.5**	"Although this guidance is specific to a trans-apical approach for mitral valve-in-ring implantation, NICE should be aware that a alternative and often preferred approach to deploy the same technology is a trans-septal technique. The literature review includes multiple studies including a trans-septal as well as trans-apical approach. In current UK practice a trans-septal approach is more common. This is less invasive, but in addition, the trans-septal approach to the left atrium and mitral valve is commonly used for other procedures, allowing operators to achieve	Thank you for your comments. 2 committee comments were added to section 3.4 and 3.5 in the guidance about transeptal approach. 3.4 *"The committee was informed that 2 different access routes are used for this procedure, and the transseptal route is less invasive than the transapical route. This guidance refers to the transapical procedure."* *3.5 "The committee noted that several devices are used for the procedure. However, currently there is only 1 device CE marked for use*

			and maintain expertise with this approach. In contrast, trans-apical access is not only more invasive but is less commonly used, particularly since trans-apical access for TAVI has reduced considerably because of adverse outcomes. NICE should consider whether to include a trans-septal approach as well as trans-apical approach for this procedure."	*through the transapical route and no devices with a CE mark are available for use through the transseptal route."* The overview of evidence provides more details about access routes in individual studies. NICE can only produce guidance on procedures where the device used is CE marked for that indication.
8	Consultee 2 Chair of British Cardiovascular Society (BCS) Guidelines committee on behalf of BCS.	**3.4**	We note that the trans-septal approach is less invasive than the transapical route, but may be more technically challenging due to the orientation of the valve relative to the different access routes.	Thank you for your comments. Section 3.4 of the guidance currently states that *"The committee was informed that 2 different access routes are used for this procedure, and the transseptal route is less invasive than the transapical route. This guidance refers to the transapical procedure."*
9	Consultee 4 Consultation support manager Royal College of Physicians	**General**	The RCP is grateful for the opportunity to respond to the above consultation. We would like to endorse the response submitted by the British Cardiovascular Society (BCS).	Thank you for your comments.

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