National Institute for Health and Care Excellence

IP 1786 / Percutaneous insertion of a closure device to repair a paravalvular leak around a replaced mitral or aortic valve

IPAC date: 8th April 2021

Com. no.	Consultee name and organisation	Sec. no.	Comments	Response Please respond to all comments
1	Consultee 1 Society for Cardiothoracic Surgery in GB and Ireland	**1.3**	"This procedure is becoming an alternative treatment option for patients with a paravalvular leak after surgery. Patients need to be discussed in a valve multidisciplinary meeting with imaging cardiology, interventional cardiology and cardiac surgical input. Careful consideration of the imaging data is required and this should be done prior to the meeting by an imaging cardiologist. The diagnosis, the origin and size of the leak and quantification of the degree of regurgitation should be confirmed at the MDT. Additional imaging data e.g. Cardiac CT scan for sizing of the defect may also be needed.	Thank you for your comments. IPAC considered and amended section 1.3 in the guidance.
2	Consultee 1 Society for Cardiothoracic Surgery in GB and Ireland	**2.1, 2.2**	Careful consideration of the indication for intervention should be given. The prevention of haemolysis is one of the commonest indications for this intervention. RCT evidence for the impact on symptoms, heart failure hospitalisations and mortality are awaited. Although surgery may be higher risk intervention, evidence that surgery reduces haemolysis, symptoms, heart failure hospitalisations and mortality exist and so the two procedures must be carefully balanced with surgical input.	Thank you for your comments. IPAC considered your comments but no further amendments about the indication, and specifically the prevention of haemolysis were made. Section 2.1 and 3.6 in the guidance already cover haemolysis.

3	Consultee 1 Society for Cardiothoracic Surgery in GB and Ireland	**1.4**	SCTS would agree with the recommendation that this practice is limited to a small number of sites to allow expertise to be developed, clinical data to be collected and disseminated and to create the opportunity for clinical trials to gather more evidence for the indications, clinical and cost effectiveness of this procedure"	Thank you for your comments and agreeing with the recommendation.
4	Consultee 2 NHS Professional Liverpool Heart and Chest Hospital	**1.4**	This document very clearly lays out the efficacy and safety of the procedure and utilises the current best evidence available to us. This is a specialist procedure and as such there are limited people performing it within the UK. The suggestion that these procedures should only be done in specialist centres makes sense and I would support that aim. However, in selecting those centres, it will be important in looking at the outcome data for each site performing these procedures and considering the types of case taken on, before making decisions on where they should be done and not just relying on absolute numbers of procedures. It is a procedure where patient selection is variable and some centres might take on cases which are more challenging while other may take on only low risk cases. I think it is also important to assess the other procedures being done at these centres which are similar to this procedure. An interventional cardiologist who does predominantly PCI and then does this procedure is unlikely to be as competent and trained to do these, as someone who does various other procedures involving similar technology like PFO/ASD closure, left atrial appendage occlusion, etc. Finally, the imaging support is very important for these procedures and having well trained and able imaging cardiologists should also be essential for any centre undertaking these procedures. Finally, the aortic PVL closure and mitral PVL closure are quite different and require different skill sets (although obviously the skill sets overlap). It may be considered that aortic PVL closure is undertaken in a larger number of centres than mitral PVL closure, which is less commonly performed and more	Thank you for your comments. IPAC amended section 1.4 in the guidance and added a committee comment in section 3.10.

			technically demanding and requires better imaging support on the whole.	
5	Consultee 3 Commissioning NHS England, Cardiothoracic Services CRG	**1.1**	The risks of percutaneous repair of a PVL are lower than the risks of surgical repair. This should be mentioned.	Thank you for your comments. Section 3.5 of the guidance already states this.
6	Consultee 3 Commissioning NHS England, Cardiothoracic Services CRG	**1.2**	Database: as part of the PMVL Repair Commissioning Policy there is funding for a national registry and this should be within NHS Digital (it could be part of the NICOR registries) rather than within a specialist society as Specialised Commissioning will require access to these data.	Thank you for your comments about the funding for the new registry. NICE can only recommend data collection by existing registries. NICOR is not currently funded to collect data on this procedure. NICE will consider amending this recommendation should this change.
7	Consultee 3 Commissioning NHS England, Cardiothoracic Services CRG	**1.2**	Data and safety review – would it be helpful to note what the expected outcomes from this procedure are for elective vs urgent vs emergency procedures? These are very different and organisations should expect that because the numbers of cases are small outcomes in any given year will be very variable.	Thank you for your comments. IPAC considered your comment and added a committee comment in section 3.11.
8	Consultee 3 Commissioning NHS England, Cardiothoracic Services CRG	**1.3**	MDT composition. An experienced imager should also be a part of the team.	Thank you for your comments. See response to comment 1.
9	Consultee 3 Commissioning NHS England, Cardiothoracic Services CRG	**1.4**	These cases are difficult, a first proctored case is not enough support for new operators. It would be helpful for the UK to establish a proctor network of those who have done >50 cases to support other centres.	Thank you for your comments about the difficult nature of this procedure and the need for proctoring. Section 1.4 in the guidance has been slightly amended.
10	Consultee 3 Commissioning NHS England,	**2.4, 2.5**	Independent operators must be able to address mitral and aortic valves via anterograde and retrograde approaches to reduce the numbers of procedure failures.	Thank you for your comments. Section 2.4 in the guidance states that for mitral valves, an antegrade approach is most commonly used and 2.5 states that

	Cardiothoracic Services CRG			for aortic valves, a retrograde approach is usually used.
11	Consultee 3 Commissioning NHS England, Cardiothoracic Services CRG	**2.5**	Fluoroscopy only aortic PVL is also possible.	Thank you for your comments. IPAC considered your comment but no further changes were made to section 2.5.
12	Consultee 3 Commissioning NHS England, Cardiothoracic Services CRG	**2.5**	Although single devices are adequate for most leaks, multiple leaks are common, and up to 40% of patients need multiple devices for that reason.	Thank you for your comments. Section 2.5 of the guidance has been amended.
13	Consultee 3 Commissioning NHS England, Cardiothoracic Services CRG	**3.3**	Define the mortality time point – on table, 30d, 6mth, 1yr?	Thank you for your comments. IPAC considered your comment but no further changes were made to section 3.3.

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