

Percutaneous balloon valvuloplasty for fetal critical aortic stenosis

Interventional procedures guidance

Published: 9 May 2018

www.nice.org.uk/guidance/ipg613

Your responsibility

This guidance represents the view of NICE, arrived at after careful consideration of the evidence available. When exercising their judgement, healthcare professionals are expected to take this guidance fully into account, and specifically any special arrangements relating to the introduction of new interventional procedures. The guidance does not override the individual responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

All problems (adverse events) related to a medicine or medical device used for treatment or in a procedure should be reported to the Medicines and Healthcare products Regulatory Agency using the [Yellow Card Scheme](#).

Commissioners and/or providers have a responsibility to implement the guidance, in their local context, in light of their duties to have due regard to the need to eliminate unlawful

discrimination, advance equality of opportunity, and foster good relations. Nothing in this guidance should be interpreted in a way that would be inconsistent with compliance with those duties. Providers should ensure that governance structures are in place to review, authorise and monitor the introduction of new devices and procedures.

Commissioners and providers have a responsibility to promote an environmentally sustainable health and care system and should assess and reduce the environmental impact of implementing NICE recommendations wherever possible.

This guidance replaces IPG175.

1 Recommendations

- 1.1 Current evidence on the safety and efficacy of percutaneous balloon valvuloplasty for fetal critical aortic stenosis is limited in quantity and the results are inconsistent. Therefore, this procedure should only be used in the context of research. Find out what only in research means on the NICE interventional procedures guidance page.
- 1.2 NICE encourages the peer-reviewed publication of all further research. Further research could be in the form of controlled trials, analysis of registry data or other observational studies. It should address patient selection, timing of the intervention and the natural history of the disease.

2 The condition, current treatments and procedure

The condition

- 2.1 Congenital heart defects are the most common type of birth defect and include aortic valve stenosis. Aortic valve stenosis ranges from mild to severe, known as critical aortic stenosis. Critical stenosis is rare but carries a high rate of postnatal morbidity and mortality.

- 2.2 Critical aortic stenosis in early fetal life causes left ventricular dysfunction; the increased pressure in the heart initially produces left ventricular dilatation and then myocardial damage. Myocardial damage can lead to hypoplastic left heart syndrome (HLHS), which can be associated with underdevelopment of the mitral valve and the aortic arch. The high pressure in the left side of the heart can increase further if the foramen ovale closes before birth, causing fibrosis of the myocardium and pulmonary venous hypertension with arterialisation of the pulmonary veins. This is known as aortic stenosis with restrictive interatrial communication and it has a very poor prognosis.
- 2.3 Many fetuses with critical aortic stenosis will survive until birth. However, about 10% will die before birth either from hydrops associated with restrictive interatrial communication or from a chromosomal abnormality.

Current treatments

- 2.4 At birth, some babies with critical aortic stenosis will not be able to have biventricular heart repair and about 50% of babies will die during the first year of life, despite surgical treatment. This prognosis can lead parents to ask for a termination of pregnancy.
- 2.5 For babies born with an adequate biventricular heart and aortic valve disease, postnatal balloon valvuloplasty is the initial preferred option to encourage remodelling and growth of the left ventricle. Further balloon valvuloplasty is often needed, with later valve replacement.
- 2.6 Staged reconstruction to create a single ventricle circulation can improve survival for babies with HLHS. This takes multiple operations over several years and involves complex high-risk open-heart surgery.
- 2.7 Fetal aortic balloon valvuloplasty may be considered when there is a high risk of fetal deterioration before delivery and an increased likelihood of postnatal mortality and morbidity. Improvements in imaging have helped identify fetuses for whom this procedure is suitable.
- 2.8 The aim of fetal aortic balloon valvuloplasty is to prevent progressive damage to the ventricle. This may allow postnatal surgical intervention to

have more chance of success.

The procedure

- 2.9 Fetal aortic balloon valvuloplasty is done at 21 to 32 weeks' gestation. Under maternal local anaesthesia (with or without sedation), a needle is inserted through the mother's abdominal wall into the uterine cavity with ultrasound guidance. Analgesia is injected into the fetus before advancing the needle through the fetal chest wall into the left ventricle. A guidewire is inserted through the needle and across the aortic valve. A balloon catheter is then inserted and inflated to dilate the stenotic valve. The catheter and needle are then withdrawn.
- 2.10 Fetal positioning is critical for the success of the procedure.

3 Committee considerations

The evidence

- 3.1 To inform the committee, NICE did a rapid review of the published literature on the efficacy and safety of this procedure. This comprised a comprehensive literature search and detailed review of the evidence from 10 sources, which was discussed by the committee. The evidence included 1 systematic review and meta-analysis, 1 retrospective propensity-matched comparative study, 6 case series, data from the international fetal cardiac intervention registry, and safety data from 1 conference abstract. These are presented in [table 2 of the interventional procedures overview](#). Other relevant literature is in additional relevant papers in the overview.
- 3.2 The specialist advisers and the committee considered the key efficacy outcomes to be: fetal survival to delivery, achieving a biventricular circulation, the need for subsequent complex cardiac surgical procedures, long-term survival and quality of life.
- 3.3 The specialist advisers and the committee considered the key safety

outcomes to be: fetal death, premature delivery, maternal safety.

3.4 No patient commentary was sought.

Committee comments

3.5 There is uncertainty about the natural progression of fetal aortic stenosis and about who may benefit from the procedure, so a study about the natural history of fetal aortic stenosis would be useful.

3.6 This is a very highly specialised and technically challenging procedure that is done on a small number of fetuses in specialised centres. It involves collaboration between specialists in fetal medicine and paediatric cardiology. The committee noted that there is some evidence that outcomes improve with experience of doing the procedure.

3.7 This procedure is rarely done in the UK, with 6 finished consultant episodes for 'Other specified therapeutic percutaneous operations on fetus (R04.8)' recorded in 2015/16.

ISBN: 978-1-4731-2952-8

Endorsing organisation

This guidance has been endorsed by [Healthcare Improvement Scotland](#).