

## NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

### Interventional procedures consultation document

# Percutaneous balloon valvuloplasty for fetal aortic stenosis

Aortic stenosis is narrowing of the valve between the main pumping chamber of the heart and the main artery (aorta) supplying blood to the body. It reduces the amount of blood flowing out of the heart and around the body. Aortic stenosis may be present in a baby before it is born. This procedure involves inserting a thin tube with a special balloon through the mother's skin into the womb, then through the baby's chest wall and into its heart. The balloon is then inflated to expand the narrowed valve and then deflated before being removed. The aim is to help the heart develop properly.

The National Institute for Health and Care Excellence (NICE) is looking at percutaneous balloon valvuloplasty for fetal aortic stenosis. NICE's interventional procedures advisory committee has considered the evidence and the views of specialist advisers, who are consultants with knowledge of the procedure.

The committee has made draft recommendations and we now want to hear your views. The committee particularly welcomes:

- comments on the draft recommendations
- information about factual inaccuracies
- additional relevant evidence, with references if possible.

**This is not our final guidance on this procedure. The recommendations may change after this consultation.**

After consultation ends:

- The committee will meet again to consider the original evidence and its draft recommendations in the light of the consultation comments.
- The committee will prepare a second draft, which will be the basis for NICE's guidance on using the procedure in the NHS.

For further details, see the [Interventional Procedures Programme process guide](#).

Through our guidance, we are committed to promoting race and disability equality, equality between men and women, and to eliminating all forms of discrimination. One of the ways we do this is by trying to involve as wide a range of people and interest groups as possible in developing our interventional procedures guidance. In particular, we encourage people and organisations from groups who might not normally comment on our guidance to do so.

To help us promote equality through our guidance, please consider the following question:

Are there any issues that require special attention in light of NICE's duties to have due regard to the need to eliminate unlawful discrimination, advance equality of opportunity, and foster good relations between people with a characteristic protected by the equalities legislation and others?

Please note that we reserve the right to summarise and edit comments received during consultations or not to publish them at all if in the reasonable opinion of NICE, there are a lot of comments, or if publishing the comments would be unlawful or otherwise inappropriate.

Closing date for comments: 15/02/2018

Target date for publication of guidance: May 2018

## 1 Draft recommendations

- 1.1 Current evidence on the safety and efficacy of percutaneous balloon valvuloplasty for fetal aortic stenosis is limited in quantity and the results are inconsistent. Therefore, this procedure should only be used in the context of research.
- 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; severe stenosis is rare but carries a high rate of postnatal morbidity and mortality.
- 2.2 Severe 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 severe 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, most babies with severe aortic stenosis will not be able to have biventricular heart repair and approximately 50% of babies will die during the first year of life despite surgical treatment. This

prognosis can lead parents of a fetus with aortic stenosis 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 for HLHS needs 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 ventricular muscle and development of pulmonary vascular hypertension. This may allow postnatal surgical intervention to have a greater chance of success.

### ***The procedure***

- 2.9 Fetal aortic balloon valvuloplasty is done at 21–32 weeks' gestation. Under maternal local anaesthesia and 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 9 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 and data from the international fetal cardiac intervention registry. These are presented in table 2 of the [interventional procedures overview \[add URL\]](#). 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: achieving a biventricular circulation, fetal survival to delivery, long-term survival and quality of life, and the need for subsequent complex cardiac surgical procedures.
- 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.

- 3.5 This guidance is a review of NICE's interventional procedures guidance on [percutaneous fetal balloon valvuloplasty for aortic stenosis](#).

### ***Committee comments***

- 3.6 There is uncertainty about the natural progression of fetal aortic stenosis and about who may benefit from the procedure.
- 3.7 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.
- 3.8 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.

Tom Clutton-Brock

Chairman, interventional procedures advisory committee

February, 2018