

Understanding NICE guidance

Information for people who use NHS services

Keyhole surgery to treat severe tracheomalacia (weakness of the windpipe)

NICE 'interventional procedures guidance' advises the NHS on when and how new procedures can be used in clinical practice.

This leaflet is about when and how keyhole surgery can be used in the NHS to treat patients with severe tracheomalacia. It explains guidance (advice) from NICE (the National Institute for Health and Clinical Excellence).

Interventional procedures guidance makes recommendations on the safety of a procedure and how well it works. An interventional procedure is a test, treatment or surgery that involves a cut or puncture of the skin, or an endoscope to look inside the body, or energy sources such as X-rays, heat or ultrasound. The guidance does not cover whether or not the NHS should fund a procedure. Decisions about funding are taken by local NHS bodies (primary care trusts and hospital trusts) after considering how well the procedure works and whether it represents value for money for the NHS.

NICE has produced this guidance because the procedure is quite new. This means that there is not a lot of information yet about how well it works, how safe it is and which patients will benefit most from it.

This leaflet is written to help parents whose children have been offered this procedure to decide whether to agree (consent) to it or not. It does not describe severe tracheomalacia or the procedure in detail – a member of your child's healthcare team should also give you full information and advice about these. The leaflet includes some questions you may want to ask your child's doctor to help you reach a decision.



What has NICE said?

There are still uncertainties about how safe this procedure is and how well it works because there is not a lot of evidence available. If a doctor wants to use keyhole surgery for severe tracheomalacia, they should make sure that extra steps are taken to explain these uncertainties to you. The doctor should also explain the alternative ways of managing severe tracheomalacia and the fact that your child may still need additional treatments. This should happen before you are asked to agree to your child having the procedure. You should be given this leaflet and other written information as part of the discussion. There should also be special arrangements for monitoring what happens to your child after the procedure.

NICE has also said that this procedure should be carried out by a team that includes a surgeon experienced in performing this sort of keyhole surgery in children.

Other comments from NICE

The National Commissioning Group is an organisation that plans, funds and monitors NHS treatment of very rare conditions. It has asked Great Ormond Street Hospital to provide a service for complicated airway problems, including severe tracheomalacia.

This procedure may not be the only possible treatment for severe tracheomalacia. Your healthcare team should talk to you about whether it is suitable for your child and about any other treatment options available.

Keyhole surgery for severe tracheomalacia

The procedure is not described in detail here – please talk to your child's specialist for a full description.

Tracheomalacia is a weakness and floppiness in the main airway (the trachea). It is usually diagnosed at birth but it may also develop later in life. In newborn babies, tracheomalacia happens because the cartilage that should normally hold the airway relatively rigid and open has not developed properly. This can cause problems with breathing such as wheezing, high-pitched breathing (doctors call this stridor), coughing, respiratory tract infections and prolonged pauses in breathing (which doctors call dying spells). Symptoms are often worse when the baby is crying, feeding or coughing. Some babies may be only mildly affected but in some the problems are severe. Mild to moderate problems usually improve with time as the trachea grows and the cartilage strengthens, so for these children treatment involves the use of humidified air, chest physiotherapy and medicine to control infections. Oxygen may be given, and sometimes a special mask may be used to deliver air under increased pressure to ease the effort of breathing (continuous positive airway pressure or CPAP). If the symptoms are severe or if the non-surgical treatments do not work, surgery may be required.

Keyhole surgery for tracheomalacia is carried out under general anaesthesia. The surgeon makes some small cuts on your child's chest. A tiny camera connected to a video recorder and monitor is inserted through one of the cuts. By watching what is happening on the monitor, the

surgeon performs the operation using special instruments inserted through the remaining holes. This is keyhole surgery, and the medical name that your child's doctors may use is thoracoscopic surgery. Once the instruments are in place, the surgeon uses permanent stitches to pull the aorta (the largest artery in the body) forward towards the breastbone. Pulling the aorta forward pulls on the trachea which passes behind it and provides space for the trachea to expand. The medical name for this procedure is aortopexy. Aortopexy can be done by open surgery, or keyhole (thoracoscopic) surgery.

You might decide to have this procedure, to have a different procedure, or not to have a procedure at all.

What does this mean for my child?

Your child's doctor should tell you that NICE has decided that the benefits and risks of this procedure are uncertain. This does not mean that the procedure should not be done, but that your child's doctor should fully explain what is involved in having the procedure and discuss the possible benefits and risks with you. You should only be asked if you want to agree to your child having this procedure after this discussion has taken place. You should be given written information, including this leaflet, and have the opportunity to discuss it with your child's doctor before making your decision.

You may want to ask the questions below

- What does the procedure involve?
- What are the benefits my child might get?
- How good are my child's chances of getting those benefits? Could having the procedure make my child feel worse?
- Are there alternative procedures?
- What are the risks of the procedure?
- Are the risks minor or serious? How likely are they to happen?
- What care will my child need after the operation?
- What happens if something goes wrong?
- What may happen if my child doesn't have the procedure?

Summary of possible benefits and risks

Some of the benefits and risks seen in the studies considered by NICE are briefly described below. NICE looked at five studies on this procedure.

How well does the procedure work?

The largest study that NICE looked at was of six children. The study followed the children's progress for 27 months after the procedure. Two of the six children had a life-threatening event which meant that the procedure had to be repeated. There were no other problems and at 27 months after the procedure all six children were reported to be 'doing

well'. NICE also looked at four studies involving a total of five children who had the procedure. The children's progress was followed for between 12 and 27 months after the procedure. The four studies showed that all the children responded well to the procedure and that their symptoms had improved.

As well as looking at these studies, NICE also asked expert advisers for their views. These advisers are clinical specialists in this field of medicine. The advisers said that the aims of the procedure are to improve the symptoms of severe tracheomalacia, for the child to be able to breathe unaided and for the child to grow normally.

Risks and possible problems

There were no problems reported in the larger study of six children and in three of the small studies. One of the small studies reported continued need for a breathing tube after the operation, but this was resolved with steroid medicine.

As well as looking at these studies, NICE also asked expert advisers for their views. These advisers are clinical specialists in this field of medicine. The advisers said that potential problems are life-threatening bleeding that cannot be controlled without opening the chest, injury to the nerves that control the movement of the diaphragm during breathing, air in the chest cavity from injury to the lung, and infection.

More information about severe tracheomalacia

Your local Patient Advice and Liaison Service (PALS) may also be able to give you further advice and support.

About NICE

NICE produces guidance (advice) for the NHS about preventing, diagnosing and treating different medical conditions. The guidance is written by independent experts including healthcare professionals and people representing patients and carers. They consider how well an interventional procedure works and how safe it is, and ask the opinions of expert advisers. Interventional procedures guidance applies to the whole of the NHS in England, Wales, Scotland and Northern Ireland. Staff working in the NHS are expected to follow this guidance.

To find out more about NICE, its work and how it reaches decisions, see www.nice.org.uk/aboutguidance

This leaflet is about 'Thoracoscopic aortopexy for severe primary tracheomalacia'. This leaflet and the full guidance aimed at healthcare professionals are also available at www.nice.org.uk/IIPG243

You can order printed copies of this leaflet from the NHS Response Line (phone 0870 1555 455 and quote reference N1431).