NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Interventional procedures consultation document

Percutaneous endovascular forearm arteriovenous fistula creation for haemodialysis access

Haemodialysis removes waste products and excess fluid from the blood when the kidneys have stopped working properly. An arteriovenous fistula is a connection created to allow haemodialysis by joining a vein to an artery, usually in the forearm. Blood from the artery goes into the vein, which becomes bigger over a few weeks. This makes it possible to put 2 large needles into the vein so that blood can be taken out of the body, sent through the haemodialysis machine, and returned. Usually, the arteriovenous fistula is created surgically as an open procedure. In this procedure, the arteriovenous fistula is created by inserting 2 thin tubes (catheters) through the forearm skin (percutaneous). One tube goes into an artery and the other goes into a vein (endovascular). The tubes are positioned close to each other, sometimes using magnets, to bring the artery and vein together. Radiofrequency energy, or heat and pressure, through the tubes is then used to join the artery and vein together creating the fistula. The aim is to avoid the need for surgery.

NICE is looking at percutaneous endovascular forearm arteriovenous fistula creation for haemodialysis access.

NICE's interventional procedures advisory committee met to consider the evidence and the opinions of professional experts, who are consultants with knowledge of the procedure.

This document contains the draft guidance for consultation. Your views are welcome, particularly:

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

NICE is committed to promoting equality of opportunity, eliminating unlawful discrimination and fostering good relations between people with particular protected characteristics and others.

Issue date: May 2021

This is not NICE's final guidance on this procedure. The draft guidance may change after this consultation.

After consultation ends, the committee will:

- meet again to consider the consultation comments, review the evidence and make appropriate changes to the draft guidance
- prepare a second draft, which will go through a resolution process before the final guidance is agreed.

Please note that we reserve the right to summarise and edit comments received during consultation 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: 25 June 2021

Target date for publication of guidance: October 2021

1 Draft recommendations

1.1 Evidence on the safety of percutaneous endovascular forearm arteriovenous fistula creation for haemodialysis access raises no major safety concerns. However, evidence on its efficacy is limited in quantity and quality. Therefore, this procedure should only be used with special arrangements for clinical governance, consent, and audit or research. Find out what special arrangements mean on the NICE interventional procedures guidance page.

1.2 Clinicians wishing to do percutaneous endovascular forearm arteriovenous fistula creation for haemodialysis should:

- Inform the clinical governance leads in their healthcare organisation.
- Give patients (and their families and carers as appropriate) clear written information to support shared decision making, including NICE's information for the public.
- Ensure that patients (and their families and carers as appropriate) understand the procedure's safety and efficacy, and any uncertainties about these.
- Audit and review clinical outcomes of all patients having the procedure. The main efficacy and safety outcomes identified in this guidance can be entered into NICE's interventional procedure outcomes audit tool (for use at local discretion).
- Discuss the outcomes of the procedure during their annual appraisal to reflect, learn and improve.

1.3 Healthcare organisations should:

- Ensure systems are in place that support clinicians to collect and report data on outcomes and safety for every patient having this procedure.

- Regularly review data on outcomes and safety for this procedure.

1.4 Patient selection should be done by a multidisciplinary team including a vascular access surgeon, nephrologist and interventional radiologist.

1.5 Report any problems with a medical device using the Medicines and Healthcare products Regulatory Agency's Yellow Card Scheme.

1.6 NICE encourages further research into percutaneous endovascular forearm arteriovenous fistula creation for haemodialysis access. This should report details of patient selection, particularly about vascular anatomy, technique used, need for training, patency of the fistula and its subsequent ease of use, and quality of life.

2 The condition, current treatments and procedure

The condition

2.1 Chronic (long-term) haemodialysis is used to treat advanced chronic kidney disease in most people who have renal replacement therapy.

Current treatments

2.2 An arteriovenous fistula is considered the best type of vascular access for haemodialysis. It is usually created surgically by joining a vein and artery together in the forearm. An alternative is minimally invasive, percutaneous endovascular creation of an arteriovenous fistula.

The procedure

2.3 The procedure is usually done in an outpatient setting under local anaesthesia or conscious sedation. A tiny needle is used to puncture the skin in the proximal forearm. Using ultrasound and fluoroscopic guidance, 2 thin, flexible, specially designed catheters (one arterial and the other venous) are then advanced and positioned by guidewires in the chosen forearm vessels (the radial, ulnar or brachial artery and adjacent vein). The catheters are aligned close to each other (sometimes using inbuilt magnets). The arterial and venous walls are then fused side to side using heat and pressure, or a small burst of radiofrequency energy released from the catheters. This creates an arteriovenous fistula between the target vessels. The catheters are then removed. High-flow arterial blood passes through the vein and, with time, it arterialises. This allows needles to be inserted into the vein to provide vascular access during haemodialysis.

2.4 The exact technique may vary slightly depending on the device used.

3 Committee considerations

The evidence

3.1 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 8 sources, which was discussed by the committee. The evidence included 1 systematic review, 1 prospective registry study, 3 retrospective case series, 1 propensity scored matching cohort study and 2 comparative case series. It is presented in the summary of key evidence section in the interventional procedures overview. Other relevant literature is in the appendix of the overview.

3.2 The professional experts and the committee considered the key efficacy outcomes to be: arteriovenous fistula maturation rate, ease of arteriovenous fistula use, longevity (patency) of arteriovenous fistula, need for re-intervention and quality of life in relation to the arteriovenous fistula.

3.3 The professional experts and the committee considered the key safety outcomes to be: pain, bleeding, hematoma, infection, arterial thrombosis and subclavian steal syndrome.

3.4 Sixteen commentaries from patients who have had this procedure were discussed by the committee. One patient organisation representing patients who have had this procedure provided submissions and these were also discussed by the committee.

Committee comments

3.5 The committee noted that more than 1 device is available for this procedure.

3.6 The committee heard that the procedure is only used to create a fistula in the forearm.

3.7 It would be helpful if data were collected as part of a registry.

3.8 The committee was informed in patient commentary that the procedure may have a better aesthetic result than a surgically created fistula.

Tom Clutton-Brock
Chair, interventional procedures advisory committee
May 2021

ISBN: