



Percutaneous endovascular forearm arteriovenous fistula creation for haemodialysis access

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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 <u>Yellow Card Scheme</u>.

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 <u>assess and reduce the environmental</u> impact of implementing NICE recommendations wherever possible.

1 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 wanting 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 <u>shared decision making</u>, including <u>NICE's information</u> 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 procedures 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.
- 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 <u>Medicines and Healthcare</u> products Regulatory Agency's Yellow Card Scheme.
- NICE encourages further research, preferably randomised controlled trials, 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 many people who have renal replacement therapy.

Current treatments

An arteriovenous fistula is considered the best type of vascular access for haemodialysis. The preferred way of creating such access is to surgically join an

artery and vein together in the distal forearm (radiocephalic fistula). However, other anatomical sites may be used. Alternative surgical approaches for vascular access include arteriovenous grafts and placing tunnelled catheters into a large vein. A minimally invasive, percutaneous, endovascular procedure is another way of creating an arteriovenous fistula.

The procedure

- This procedure can be done using different systems, and is usually done in a day-case facility under local anaesthesia, with or without conscious sedation. Using ultrasound or fluoroscopic guidance, 2 small needles are inserted into an artery and a vein in the proximal forearm, that is, the radial, ulnar or brachial artery and adjacent vein. Thin, flexible, specially designed catheters are then advanced and positioned by guidewires in the chosen vessels. The catheters are aligned close to each other (using inbuilt magnets or mechanically, depending on the system). 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.
- 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 <u>summary of key evidence</u> <u>section in the interventional procedures overview</u>. Other relevant literature is in the appendix of the overview.

- 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 reintervention, and quality of life in relation to the arteriovenous fistula.
- The professional experts and the committee considered the key safety outcomes to be: pain, bleeding, haematoma, 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.
- 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.
- The committee was informed in patient commentary that the procedure may have a better aesthetic result than a surgically created fistula.

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Endorsing organisation

This guidance has been endorsed by <u>Healthcare Improvement Scotland</u>.