



Autologous blood injection for plantar fasciitis

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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 impact of implementing NICE recommendations</u> wherever possible.

1 Guidance

- The evidence on autologous blood injection for plantar fasciitis raises no major safety concerns. The evidence on efficacy is inadequate in quantity and quality. Therefore, this procedure should only be used with special arrangements for clinical governance, consent and audit or research.
- 1.2 Clinicians wishing to undertake autologous blood injection for plantar fasciitis should take the following actions.
 - Inform the clinical governance leads in their Trusts.
 - Ensure that patients understand the uncertainty about the procedure's
 efficacy, make them aware of alternative treatments and provide them with
 clear written information. In addition, the use of NICE's information for the
 public is recommended.
 - Audit and review clinical outcomes of all patients having autologous blood injection for plantar fasciitis (see <u>section 3.1</u>).
- NICE encourages further research comparing autologous blood injection (with or without techniques to produce platelet-rich plasma) against established treatments for managing plantar fasciitis. Trials should clearly describe patient selection, including duration of symptoms and any prior treatments. Outcomes should include specific measures of pain and function.

2 The procedure

2.1 Indications and current treatments

- 2.1.1 Plantar fasciitis is characterised by a painful inflammatory process involving the plantar fascia, causing pain on the underside of the heel. It is usually caused by overuse, injury or biomechanical abnormalities and may be associated with microtears, or fibrosis. It is usually a self-limiting condition.
- 2.1.2 Conservative treatments include rest, analgesics, anti-inflammatory medication, use of orthotic devices, eccentric exercise, stretching and physiotherapy. Local injection of steroids, extracorporeal shockwave therapy and surgery to release the plantar fascia from the bone or to relieve muscular tightness are sometimes used for patients with refractory symptoms.

2.2 Outline of the procedure

- 2.2.1 Autologous blood injection for plantar fasciitis is claimed to promote healing through the action of growth factors. It can be performed using either autologous whole blood or platelet-rich plasma. The latter aims to deliver a greater concentration of growth factors.
- 2.2.2 A variable amount of blood is withdrawn from the patient by standard venesection. Sometimes the blood is centrifuged to produce a platelet-rich sample. About 2 ml to 3 ml of whole blood or platelet-rich plasma is injected into the plantar fascia, sometimes with ultrasound guidance. Local anaesthetic is usually used. 'Dry needling' (repeatedly passing a needle through the tissue to disrupt the fibres and induce bleeding) may be performed before injection of the blood. A 'peppering' technique is sometimes used to inject the autologous blood; this involves inserting the needle into the fascia, injecting some of the blood, withdrawing without emerging from the skin, slightly redirecting and reinserting. After the procedure, patients are usually advised to avoid high-impact activities for a few weeks, and to follow a programme of stretching exercises. The procedure may be repeated if needed.

2.3 Efficacy

Sections 2.3 and 2.4 describe efficacy and safety outcomes from the published literature that the Committee considered as part of the evidence about this procedure. For more detailed information on the evidence, see the overview.

- A randomised controlled trial of 64 patients treated by autologous blood injection or corticosteroid injection reported that mean pain scores decreased from 7.3 and 6.9 at baseline to 3.6 and 2.4 respectively at 6-month follow-up (p<0.0001 for both groups; measured on a visual analogue scale from 0 to 10, with 0 indicating no pain and 10 the worst imaginable pain). The proportion of patients with no change in score was 10% in both groups (3 out of 30 and 3 out of 31 respectively). The mean tenderness threshold improved from 3.1 kg/cm² at baseline to 6.5 kg/cm² in the autologous blood injection group and from 3.7 kg/cm² to 8.6 kg/cm² in the corticosteroid group at 6-month follow-up (p<0.0001 for both groups).
- A randomised controlled trial of 45 patients treated by autologous blood injection, corticosteroid injection or peppering alone reported that mean pain scores reduced from 7.6, 7.3 and 6.4 at baseline to 2.4, 2.6 and 2.0 respectively at 6-month follow-up (p<0.001 for all groups; measured on a visual analogue scale from 0 to 10). The Rearfoot scores (scale 0 to 100 with higher scores indicating less pain and better function) improved from 72, 66 and 64 at baseline to 81, 80 and 78 respectively at 6-month follow-up (p=0.025, 0.030 and 0.018 respectively). There were no statistically significant differences between the groups.
- A non-randomised comparative trial of 100 patients treated by autologous blood injection, local anaesthetic with peppering, corticosteroid injection or corticosteroid injection with peppering reported an 'excellent' or 'good' outcome in 60% (15 out of 25), 52% (13 out of 25), 80% (20 out of 25) and 88% (22 out of 25) of patients respectively at 6-month follow-up (measured using a modified Roles and Maudsley scale, which measures pain and limitation of activity). There was a statistically significant difference between corticosteroid injection and autologous blood injection and local anaesthetic with peppering, with more successful outcomes in the corticosteroid groups (p<0.05).

- The randomised controlled trial of 45 patients treated by autologous blood injection, corticosteroid injection or peppering alone reported that 67% (10 out of 15), 0% (0 out of 14) and 47% (7 out of 15) of patients respectively needed a third injection.
- 2.3.5 The Specialist Advisers listed key efficacy outcomes as reduction in heel pain and improved function.

2.4 Safety

- 2.4.1 The randomised controlled trial of 64 patients treated by autologous blood injection or corticosteroid injection reported that all patients found the procedure to be painful. After the procedure, pain needing analgesia, ice application or both was reported in 53% (16 out of 30) and 13% (4 out of 31) of patients respectively (p value not reported). The mean duration of symptoms was 7 days in the autologous blood injection group and 5 days in the corticosteroid injection group.
- A non-randomised comparative study of 60 patients treated by autologous blood injection or corticosteroid injection and a case series of 25 patients reported that there were no adverse events.
- The Specialist Advisers listed theoretical adverse events as rupture of the plantar fascia, local neurovascular damage, infection, and bruising.

2.5 Other comments

- 2.5.1 The Committee noted that plantar fasciitis is normally a self-limiting condition, which introduces some uncertainty about the relative effect of interventions in the published studies. The comparators used in most of the studies were not useful in determining whether autologous blood injection for plantar fasciitis is efficacious. In addition, the procedure was often used in combination with other therapies.
- 2.5.2 The Committee was advised that this procedure should only be considered for

patients with refractory symptoms.

3 Further information

This guidance requires that clinicians undertaking the procedure make special arrangements for audit. NICE has identified relevant <u>audit criteria</u> and has developed an <u>audit tool</u> (which is for use at local discretion).

Sources of evidence

The evidence considered by the Interventional Procedures Advisory Committee is described in the <u>overview</u>.

Information for patients

NICE has produced <u>information for the public on this procedure</u>. It explains the nature of the procedure and the guidance issued by NICE, and has been written with patient consent in mind.

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Endorsing organisation

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