NICE National Institute for Health and Care Excellence

NICE guidance

Leukapheresis for inflammatory bowel disease

HealthTech guidance
Published: 22 June 2005

www.nice.org.uk/guidance/htg75

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 Yellow Card Scheme.

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 assess and reduce the environmental impact of implementing NICE recommendations wherever possible.

Contents

This guidance replaces IPG126.

1 Recommendations

1.1 Current evidence suggests that there are no major safety concerns for the use of leukapheresis for inflammatory bowel disease.

1.2 Leukapheresis may be beneficial in carefully selected patients with ulcerative colitis, but the evidence on efficacy is not yet adequate to support its use in these patients without special arrangements for consent and for audit or research as set out in 1.4.

1.3 There is inadequate evidence to draw any conclusions about the efficacy of leukapheresis in patients with Crohn's disease and it should only be used in accordance with special arrangements for consent and audit as set out in 1.4.

1.4 Clinicians wishing to undertake leukapheresis for inflammatory bowel disease should take the following actions.

- Inform the clinical governance leads in their Trusts.
- Ensure that patients understand the uncertainty about the procedure's efficacy and provide them with clear written information. Use of NICE's information for the public is recommended.
- Audit and review clinical outcomes of all patients having leukapheresis.

1.5 Publication of current and future research studies will be useful. NICE may review the procedure upon publication of further evidence.

2 The procedure

2.1 Indications

2.1.1 Ulcerative colitis and Crohn's disease are the most common forms of inflammatory bowel disease. Ulcerative colitis causes inflammation and ulceration of the rectum and colon. Symptoms include bloody diarrhoea and rectal bleeding. Crohn's disease usually causes inflammation and ulceration of the small intestine, but it can affect any part of the digestive tract. The main symptoms are abdominal pain, diarrhoea and weight loss. Both ulcerative colitis and Crohn's disease are chronic conditions characterised by periods of clinical relapse and remission.

2.1.2 Conservative treatments include dietary measures and medication to control inflammation, which may include immunosuppressants. Patients with ulcerative colitis that does not respond to medical therapy may be treated with surgery to remove the colon. Although surgery may also be used for patients with Crohn's disease, it may not be curative and the disease often recurs in a different part of the digestive tract.

2.2 Outline of the procedure

2.2.1 Leukapheresis involves extracorporeal removal of leukocytes from the blood, either by centrifugation or through an adsorptive system. In each system, venous blood is removed in a continuous flow, anticoagulated, processed to deplete the leukocytes and returned to the circulation.

2.2.2 Different apheresis systems remove different populations of white blood cells. Leukapheresis using centrifugation removes a proportion of neutrophils and lymphocytes. Filter columns, which may contain cellulose acetate beads or a polyester fibre filter, remove a large proportion of granulocytes and monocytes and some also remove lymphocytes. The exact mode of action of these procedures is unknown.

2.3 Efficacy

2.3.1 In 1 randomised controlled trial of patients with ulcerative colitis, 74% (29 of 39) of patients treated with leukapheresis had an 'excellent' or 'moderate' improvement in symptoms, compared with 38% (14 of 37) of patients treated with high-dose steroids (p=0.005).

2.3.2 In 4 case series, 54% (24 of 44) to 82% (32 of 39) of patients with ulcerative colitis had an initial remission of disease after treatment. In 1 study, the proportion of patients in clinical remission dropped from 82% (32 of 39) at 12 weeks to 67% (26 of 39) at 12 months after the final treatment. In 2 further studies, 30% (10 of 33) and 39% (13 of 33) of patients relapsed during maintenance therapy after initial complete remission.

2.3.3 In a small randomised controlled trial of patients with Crohn's disease, 100% (12 of 12) of patients treated with leukapheresis were successfully withdrawn from steroid therapy, compared with 67% (10 of 15) of patients who were not treated with leukapheresis (p=0.074). There was no significant difference between the 2 groups in disease recurrence at 18-month follow-up. For more details, see the overview.

2.3.4 The specialist advisors stated that some uncertainty remained about the efficacy of leukapheresis for inflammatory bowel disease because data from randomised controlled trials were insufficient.

2.4 Safety

2.4.1 Most studies reported only mild adverse events such as dizziness, light headedness, headache and flushing. In 3 case series, the proportion of patients experiencing at least 1 non-severe adverse event ranged from 9% (5 of 53) to 18% (7 of 39).

2.4.2 In a randomised controlled trial, the incidence of adverse events was significantly lower in the group treated with leukapheresis than in the group treated with high-dose steroids (24% versus 47%, p<0.001). In the same trial, adverse events were described as moderate or severe in 12% (5 of 42) of patients treated with

leukapheresis: 1 patient had toxic shock, 1 patient had chest pain, 1 patient had anaemia and 2 patients had a headache. For more details, see the overview.

2.4.3 The specialist advisors stated that potential adverse events included infection, headache, palpitations, nausea, vomiting, fever, chills, respiratory distress and chest discomfort.

2.5 Other comments

2.5.1 It was noted that leukapheresis is an established technique for other conditions.

2.5.2 It was also noted that there are different techniques for leukapheresis, and these may have different risk and benefit profiles.

3 Further information

Sources of evidence

The evidence considered by the committee is in the overview.

Information for patients

NICE has produced information on this procedure for patients and carers. It explains the nature of the procedure and the guidance issued by NICE, and has been written with patient consent in mind.

Update information

Minor changes since publication

January 2026: Interventional procedures guidance 126 has been migrated to HealthTech guidance 75. The recommendations and accompanying content remain unchanged.

ISBN: 978-1-4731-9062-7

Endorsing organisation

This guidance has been endorsed by Healthcare Improvement Scotland.