NICE guidance

Deep dermal injection of non-absorbable gel polymer for HIV-related lipoatrophy

Interventional procedures guidance
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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 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

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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.

This guidance replaces IPG291.

1 Guidance

1.1 Current evidence on the efficacy of deep dermal injection of non-absorbable gel polymer (NAGP) for HIV-related facial lipoatrophy is adequate. With regard to safety, infections that may need surgical removal of the implant are a risk in the longer term and other complications, including granuloma formation and migration, are common. Therefore, this procedure should be performed only with special arrangements for clinical governance, consent and audit or research.

1.2 Clinicians wishing to undertake deep dermal injection of non-absorbable gel polymer for HIV-related facial lipoatrophy should take the following actions.

- Inform the clinical governance leads in their Trusts.
- Ensure that patients understand that complications may occur in the short or long term – specifically infection, granuloma formation and migration – and that the implant may need to be removed. They should inform patients about the range of treatment options available. In addition, the use of NICE's information for the public is recommended.
- Audit and review clinical outcomes of all patients having deep dermal injection of non-absorbable gel polymer for HIV-related facial lipoatrophy (see section 3.1).

1.3 Clinicians using this procedure should be trained in the technique of injecting

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non-absorbable gel polymers. Injection should be carried out with strict aseptic technique in an appropriate environment.

1.4 Further research and publication of observational data would be useful. Publications should describe details of patient selection, particularly in relation to previous treatments. They should also describe clinical outcomes (including all complications) and patient experience in the longer term. NICE may review the procedure on publication of further evidence.

2 The procedure

2.1 Indications and current treatments

2.1.1 Lipoatrophy is the localised loss of fat from within subcutaneous tissue. It can be a congenital condition or can be associated with subcutaneous injection sites. Facial lipoatrophy is commonly seen after HIV treatment, particularly with the older antiretroviral drugs. It involves wasting of the soft tissues of the cheeks, temples and around the eyes, producing changes in appearance that have severe psychological and social consequences for some patients.

2.1.2 Current treatments for HIV-associated lipoatrophy include autologous fat transfer, dermal fat grafting, transfer of skin flaps and injection of temporary dermal fillers (such as collagen) or semi-permanent dermal fillers (such as polylactic acid).

2.2 Outline of the procedure

2.2.1 Deep dermal injection of permanent or non-absorbable gel polymer (NAGP) aims to improve the appearance of HIV-associated lipoatrophy and its related psychological effects. It is intended to achieve a long-lasting result.

2.2.2 The procedure is performed under general or local anaesthesia. Non-absorbable gel polymer is injected with a needle or cannula, deep into the subcutaneous tissue. Strict aseptic technique is used and prophylactic antibiotics are given.

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After injection, the gel is massaged into position to produce a good aesthetic result. Once in place, the gel forms a thin external membrane or capsule that isolates it from the surrounding tissues and results in a liquid-filled endoprosthesis. The volume of gel injected depends on which part of the body is being treated and the degree of lipoatrophy; for facial treatment, typically 1 ml is injected at each site at each treatment session. A course of injections over several weeks may be needed depending on the volume required.

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.

2.3.1 A non-randomised comparative study of 299 patients (130 treated by NAGP injection, 91 by polylactic acid [PLA] injection, 54 by autologous fat transfer only [AFT] and 24 by AFT plus PLA injection) reported significant improvements in facial aesthetic satisfaction ($p<0.0001$), body image satisfaction ($p<0.0001$) and depression score ($p=0.014$) at 48-week follow-up for the NAGP group. Patients were evaluated by visual analogue scale, the Assessment of Body Change and Distress questionnaire and the Beck Depression Inventory scale. A cohort study of 32 patients (5 from a pilot study and 27 from a randomised controlled trial comparing immediate against delayed dermal injection of NAGP) reported significant improvements in scores for anxiety ($p<0.001$) and depression ($p<0.001$) on the Hospital Anxiety Depression scale, the slightly modified Dermatology Quality of Life Survey ($p<0.001$), and the mental health domain ($p=0.02$) of the Medical Outcomes Study-HIV health survey at 4-year follow-up compared with baseline.

2.3.2 The cohort study of 32 patients reported significant improvements in scores for median physician and patient-graded facial lipoatrophy severity (-2 [interquartile range -2, -1; $p<0.001$] and -1 [interquartile range -3, -1; $p<0.001$]) at 4-year follow-up compared with baseline.

2.3.3 A case series of 145 patients reported that 89% of patients were 'satisfied' or 'very satisfied' with the results 4 years after receiving NAGP injections (assessed

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using a 3-point scale ranging from not satisfied to very satisfied).

2.3.4 The non-randomised comparative study of 299 patients reported a significant augmentation of cheek thickness (right cheek from 4.3±1.9 mm to 9.5 mm $p<0.0001$, left cheek from 4.4±2 mm to 9.6±3.1 mm, $p<0.0001$) from baseline to 48-week follow-up. The case series of 38 patients also reported a statistically highly significant improvement in cheek thickness (measured with ultrasound) from a pretreatment mean of 3.7 mm to 13.3 mm ($p<0.0001$) at a mean follow-up of 5 years.

2.3.5 The Specialist Advisers listed key efficacy outcomes as restoration of appearance, volume augmentation and psychometric evaluation of satisfaction.

2.4 Safety

2.4.1 Infection (confirmed by culture) was reported in 16% (5 out of 32) of patients in the cohort study of 32 patients at 4-year follow-up; the median interval between NAGP injection and occurrence of infection was 2.8 years. An additional 9% (3 out of 32) of patients had possible infection with a median time of occurrence of 3.7 years after treatment. All patients in this study with confirmed infections and 1 patient with possible infection had infections after dental treatment and were treated with antibiotics followed by surgical removal of the NAGP. The other 2 patients with possible infection were treated by antibiotic treatment alone.

2.4.2 Infections occurred in 19% (56 out of 267) of patients in a case series of 267 patients with a median follow-up of 30 months. The rate of primary infection was 0.07 per patient-year of follow-up, and the rate of definite infection was 0.02 per patient-year of follow-up. The median time from first treatment to infection was 32 months. Surgical management with antibiotics was needed for most patients. Prior facial manipulation for dental work or cosmetic surgery near the filler site in the month before infection was the most common factor associated with infection.

2.4.3 Infections after revision procedures for correction of asymmetry were reported in 22% (4 out of 18) of patients in a case series of 18 patients with follow-up of 2 months to 3 years. These occurred near the site of implant and were treated by

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antibiotics in 3 patients and by surgical removal of NAGP in 1 patient.

2.4.4 Nodules were reported in 25% (8 out of 32) of patients in the cohort study of 32 patients at 4 years. Non-visible nodules and indurations were found in 19% (28 out of 145) and 6% (9 out of 145) of patients respectively in the case series of 145 patients at a mean follow-up of 50 months after NAGP injection (no further details reported).

2.4.5 Migration of the NAGP was reported in 25% (9 out of 36) of patients at 7-year follow-up in a retrospective case series of 69 patients; mean time of onset was 12 months. This was treated by removal of the implant in 22% (8 out of 36) of patients. Intra-oral extrusion of the NAGP through the buccal mucosa of the cheek was reported in 1 patient in the case series of 18 patients at 12-month follow-up. This was removed surgically by stab incisions and curettage.

2.4.6 The Specialist Advisers listed theoretical adverse events as vascular occlusion, delayed granuloma formation, unsatisfactory cosmetic appearance and short duration of effect.

2.5 Other comments

2.5.1 The Committee recognised that facial lipoatrophy can be a very distressing condition for patients with HIV, whose quality of life may be significantly improved by effective treatment. The balance of risks and benefits of deep dermal injection of NAGP in immunocompromised patients with HIV may differ from that in patients considering the procedure for other indications.

2.5.2 The Committee noted that different types of gels used for this procedure may have different long-term effects.

2.5.3 The Committee recognised that there have been concerns about complications in the longer term after deep dermal injection of NAGP. This underpinned the recommendation for continued data collection and research, in particular to address the balance of risks and benefits in patients with HIV-related facial lipoatrophy.

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2.5.4 The Committee noted reports of infection of implanted NAGP associated with subsequent dental procedures.

3 Further information

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

Sources of evidence

The evidence considered by the Interventional Procedures Advisory Committee is described in the overview.

3.2 Information for patients

NICE has produced information for the public on this procedure. 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 Healthcare Improvement Scotland.

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