

Purchasing Guidance: Considered Judgement Form

This form is a checklist of issues that may be considered by the Purchasing Guidance Advisory Group when making purchasing recommendations



Meeting Date	21 June 2017
Topic	Effectiveness of steroid injections to the plantar fascia

Purpose

This purchasing guidance (considered judgement) document accompanies a systematic review commissioned from the International Centre for Allied Health Evidence (iCAHE), University of South Australia. The purposes are to:

1. Review the effectiveness and safety of steroid injections in the management of plantar fasciitis/fasciopathy.
2. Make purchasing recommendations on this interventional pain management (IPM) modality.

Background

Plantar fasciitis (or plantar fasciopathy) is a common disorder of the foot, causing pain and tenderness under the heel and in the sole. It is estimated to affect 15% of adults during their lifetime and accounts for around 25% of all foot injuries related to running. It typically resolves without treatment, but this can take up to 18 months, hence the need for intervention in the short and medium term to relieve pain and improve function.

The aetiology of plantar fasciitis is not well understood. Risk factors are thought to include overuse (e.g. excessive running), obesity and degenerative changes. Due to uncertainty about causation, ACC may decline claims.

Steroid injections have been used to treat plantar fasciitis where conservative therapies (e.g. rest, exercise techniques, orthotics) have failed. There is some uncertainty over their method of action. Local anaesthetic is typically added to the steroid injectate to provide temporary pain relief. Other treatment options include weight loss, non-steroidal anti-inflammatory drugs (NSAIDs) and extracorporeal shockwave therapy (ESWT).

ACC's 2005 guidance on IPM procedures made the following purchasing recommendation:

- Steroid injections may be purchased for the short term (3-6 weeks) treatment of adults with plantar fasciitis (level B recommendation supported by moderate quality evidence).

The 2005 guidance included three good practice points:

1. In the absence of sustained clinical effect the number of injections should be limited to no more than three per year.
2. It is important to exclude an inflammatory condition such as ankylosing spondylitis, as treatment should be directed at this underlying condition.
3. If rupture of the plantar fascia does occur, then the foot needs to be supported by an orthosis.

1. Effectiveness, Volume of Evidence, Applicability / Generalisability and Consistency / Clinical impact

Comment here on the extent to which the service/product/ procedure achieves the desired outcomes. Specific reference needs to be made to safety. Report number needed to treat and harm where possible, any issues concerning the quantity of evidence and its methodological quality and the extent to which the evidence is directly applicable or generalisable to the New Zealand population, and the degree of consistency demonstrated by the available evidence. Where there are conflicting results, indicate how the group formed a judgement as to the overall direction of the evidence. Comment on the clinical impact e.g. size of population, magnitude of effect, relative benefit over other management options, resource implications, balance of risk and benefit.

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Volume & quality of studies:

The iCAHE authors identified 9 systematic reviews (SRs) and 20 additional randomised controlled trials (RCTs) on steroid injections for plantar fasciitis. They also included a case control study on risk factors.

The quality of included SRs was variable, ranging from high (n=4) to acceptable (n=2) to low (n=3). The RCTs were also of variable quality (5 high, 2 acceptable and 13 low quality).

Key findings, from the higher quality studies where available, are outlined below.

Evidence of effectiveness (pain relief) from SRs

Compared to placebo:

- One adequate and one high quality SR found that steroid injections were superior to placebo in the short term (Li et al. 2015; Cochrane review by Crawford et al. 2003).

Compared to other treatments:

- Steroid injections were marginally more effective than autologous blood injections in the short term (high quality SR/meta-analysis by Tsikopoulos et al. 2016).
- There was limited evidence that steroid injections are more effective than ESWT, stretching exercises or autologous blood injections in the short term, but of similar effectiveness in the long term (high quality SR by Uden et al. 2011).

Evidence of effectiveness (pain relief & functional improvement) from RCTs

Compared to placebo:

- Steroid injections were significantly more effective than placebo injections for pain and heel function at three months post-treatment (high quality RCT by Mahindra et al. 2016)

Compared to other treatments:

- Steroid injections were more effective than joint mobilisation or stretching exercises in the short term (up to three months), but not at one year (high quality RCT by Celik et al. 2016)
- Steroid injections were comparable to extracorporeal shock wave therapy (ESWT) two months post-treatment in one high quality RCT (Eslamian et al. 2016), but superior at three months in an acceptable quality RCT (Mardani-Kivi et al. 2015)
- Steroid injections were comparable to platelet rich plasma (PRP) injections for pain outcomes at three months, but heel function was significantly better with PRP (high quality RCT by Mahindra et al. 2016)
- Steroid injections were less effective than mini-scalpel-needle release treatment at one, six and twelve months (high quality RCT by Li et al. 2014)

Evidence on safety:

Where adverse events were reported in the SRs and RCTs, they were mostly minor and transient. One low quality RCT (Biswas et al. 2011) reported two cases of plantar fascia rupture following palpation-guided steroid injection.

In an acceptable quality case control study (Lee et al. 2014) of risk factors for plantar fascia rupture involving 286 people who had been treated for plantar fasciitis, steroid injection was the only factor associated with rupture. The odds ratio was 32.96 (95% confidence interval 9.724 to 111.717). The authors concluded that steroid injections should therefore be used with caution.

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Evidence on the value of imaging (ultrasound guidance):

The evidence was conflicting and all studies were of low quality. One SR (Ang 2015) and two RCTs (Saba & Sharif 2016; Yucel et al. 2009) found no significant outcome differences between ultrasound- and palpation-guided steroid injections. However, one RCT (Chen et al. 2013) reported significantly better pain outcomes following injection using a custom ultrasound guidance device. Findings from another RCT (Tsai et al. 2006) also favoured ultrasound-guided injections, but differences were significant only for heel pain recurrence.

2. Cost

Where possible and reported in the published research literature any economic analysis of the new treatment is considered. Where possible the following will be considered; total costs of the new intervention and number of claimants likely to be affected are considered, along with comparison with the cost of current treatments or interventions, actuarial assessment of the impact of the intervention on scheme liability (including direct and indirect impact e.g. other services and access), expected “accrued benefit” in terms of quality of life, longer life or speedier return to the workforce, implications of cost to the wider health sector.

The iCAHE review found no evidence on the economic implications of using steroid injections to treat plantar fasciitis.

According to the IPM service schedule (ACC 2015), the unit price for steroid injections to the plantar fascia, with or without local anaesthetic, is \$53.80 excluding GST. It is classed under *Enthesis injections* and coded IN71. Up to five treatments may be given without prior approval. ACC does not generally fund imaging guidance for this intervention. ACC accepts and funds very low numbers of claims for this intervention, typically 1-4 claims per year.

3. Equity

The extent to which the intervention reduces disparities in health status - in particular equity of access and health outcome. The extent to which the intervention supports the objectives of the Maori access strategy and will encourage access to assessment, treatment and rehabilitation services for those groups where there is evidence of that access is problematic.

There do not appear to be any equity issues associated with this intervention.

4. Consistency with the intent of the AC Act

Purchasing decisions made by ACC must be consistent with and reflect consideration of factors described in the AC Act [Schedule 1, clause 2 (1 and 2)] and these decisions must be defensible against this statutory requirement in respect of individual claimants.

There do not appear to be any consistency issues associated with this intervention.

5. Possible purchasing options

The options are:

1. Purchase,
2. Do not purchase, or
3. Purchase on a case by case basis on the decision of the Manager Corporate Clinical Advice (or equivalent).

6. Evidence statements

Summarise the advisory group's synthesis of evidence relating to this service, product or procedure, taking the above factors into account, and indicate the evidence level that applies.

Note: HQ = high quality, AQ = acceptable quality, LQ = low quality

Evidence of effectiveness against placebo

- Steroid injection to the plantar fascia appears to be effective at reducing pain in the short-term (<3 months post-treatment) when compared to placebo, but fails to offer any significant benefit in the long-term (level A, based on one HQ SR, one HQ RCT, one AQ SR, and two LQ SRs)

Evidence of effectiveness compared with conservative (non-invasive) treatments

- Steroid injection to the plantar fascia is likely to be more effective at reducing pain in the short-term (<3 months post-treatment) compared with physical therapies; however, it has comparable effectiveness in the long-term (level B, based on one HQ SR and one HQ RCT)
- Steroid injection is more effective than use of silicone insoles at reducing pain in the short-term (<3 months post-treatment), with inconsistent results for relative long-term effectiveness (level B, based on one HQ RCT)
- Steroid injection is comparable to extracorporeal shockwave therapy in reducing pain in the long-term (≥ 3 months post-treatment), with inconsistent results regarding short-term effectiveness (level B, based on one HQ SR, one HQ RCT, and one AQ RCT)

Evidence of effectiveness compared with alternative invasive treatments

- Steroid injection is superior to autologous blood injection at reducing pain in the short-term (<3 months post-treatment); however, it has comparable effectiveness in the long-term (level B, based on two HQ SRs, one LQ SR, and one LQ RCTs)
- Steroid injection is inferior to injection with botulinum toxin type A at reducing pain in the short and long-term (level B, based on one HQ RCT)
- Steroid injection is inferior to miniscalpel-needle release treatment at reducing pain in the short and long-term (level B, based on one HQ RCT)

Evidence on safety

- Steroid injection is associated with increased risk of rupture of the plantar fascia (level D, based on one AQ case-control study)

Evidence of effectiveness by guidance method

- Evidence on differences in pain outcome for steroid injections delivered with ultrasound or palpation guidance is conflicting and of low quality.

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7. Purchasing recommendations

What recommendation(s) does the advisory group draw from this evidence?

Taking the recent evidence into account, PGAG advises that ACC updates the 2005 purchasing recommendation as follows in cases where a claim for plantar fasciitis has been accepted:

Steroid injections may be purchased for the short term (up to 12 weeks) management of pain in adults with plantar fasciitis

Good practice point:

- Evidence suggests that steroid injections are associated with an increased risk of rupture of the plantar fascia

This recommendation was ratified by the Clinical Governance Committee in July 2017.

PGAG discussions

References

ACC (2015). *Service schedule for interventional pain management services*. Wellington, ACC.

For details of other references, please see the iCAHE review:

International Centre for Allied Health Evidence (2017). *Systematic review of the literature: the effectiveness of injection of steroid with or without local anaesthetic to the plantar fascia: technical report*. Adelaide, iCAHE.