Meeting Date | 13 February 2017  
---|---  
Topic | Effectiveness of epidural steroid injections via the transforaminal route  

**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. Carry out an updated review of the effectiveness and safety of epidural steroid injections via the transforaminal route.
2. Make a purchasing recommendation on this interventional pain management (IPM) technique.

**Background**

Epidural steroid injections for lower back or leg pain are typically administered via one of three routes: interlaminar, transforaminal or caudal sacral. Transforaminal injection delivers the drug close to a specific spinal nerve root and is therefore the most carefully targeted approach. The needle is inserted into the epidural space through the foramen, the opening where the nerve root exits the spinal canal. As accurate needle placement is crucial, transforaminal injections are given under fluoroscopic guidance. Indications include disc herniation, spinal stenosis, sciatica and radiculitis.

This work is being carried out to update ACC's 2005 guidance on IPM procedures, which made the following recommendations for clinical practice but made no formal purchasing recommendation (ACC 2005):

- Transforaminal injection of steroid with local anaesthetic may be considered for the short-term treatment of adults with sciatica (grade B recommendation supported by fair quality evidence)

**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.*

**Volume & quality of studies:**

The iCAHE reviewers identified 16 systematic reviews (SRs), 14 additional randomised controlled trials (RCTs), 19 cohort studies and 10 case series/case studies.

The quality of the SRs ranged from high (n=4) to acceptable (n=8) to low (n=3). One was rejected due to unacceptable quality. The main methodological problems affecting SR quality were:
A tendency to report findings on lumbar epidural steroid injections as a broad intervention category rather than breaking them down as per the injection route used, making it difficult to assess the comparative effectiveness of the three approaches. The iCAHE reviewers therefore included only those SRs which focused on the transforaminal approach or for which data on the transforaminal approach could be extracted.

- Failure to distinguish between primary outcomes (usually pain-related) and secondary outcomes (e.g. function or delaying the need for surgery) when synthesizing study findings.
- Failure to list excluded studies.
- Failure to address the potential impacts of publication bias and publication status.
- Failure to identify or report on study authors’ conflicts of interest.

The quality of the RCTs ranged from high (n=7) to acceptable (n=4) to low (n=3). Quality shortcomings included:

- Poor definition of participants’ presenting conditions.
- Failure to deal with the effects of confounding factors, e.g. differences between intervention and control groups that weren’t due to the treatment received.
- Lack of blinding of participants and/or investigators.
- Failure to use (or report on the use of) “intention to treat” analysis.

The cohort studies were generally of low quality. Only three were scored as acceptable quality. Issues included:

- Baseline characteristics tended to be poorly described.
- Sampling was rarely reported as consecutive.
- Outcomes were often poorly defined.

Evidence of effectiveness (in terms of pain relief and/or improved function) – key SRs:

*Shamiyan et al (2014)*

This recent SR on epidural steroid injections (all approaches) for radicular lumbosacral pain was significant because of its very comprehensive search and inclusion criteria and its extensive statistical analysis of study findings and patient characteristics (it did not perform a full meta-analysis, however). The SR found that, compared to placebo or control, injections using the transforaminal approach had:

- Non-significant effects on leg pain (moderate quality evidence) and disability (low quality evidence) in the short term (>12 weeks).
- Significant effects on leg pain in the longer term (low quality evidence).
- Non-significant effects on the need for surgery within 12 months (moderate quality evidence).

The SR concluded that, based on high quality evidence, routine use of off label epidural steroid injections is not recommended for benign radicular lumbosacral pain. The iCAHE reviewers rated this SR acceptable quality.

The findings of the four SRs rated highest quality by the iCAHE reviewers are outlined below:

*Bhatia et al (2016)*

This SR/meta-analysis assessed the effectiveness of the transforaminal approach for treating lumbosacral radicular pain in patients with herniated discs. It found moderate quality evidence that transforaminal injections
provide modest pain relief in the short term (up to three months), but high to moderate quality evidence that they do not decrease physical disability at 1-3 months or decrease the incidence of surgery at 12 months.

**Bicket et al (2015)**

This SR/meta-analysis focused on the effectiveness of epidural steroid injections in reducing the need for surgery in people with spinal pain. It found that epidural steroid injections may provide a small surgery-sparing effect in the short term.

**Chien et al (2014)**

This SR compared transforaminal with interlaminar route injections for treating patients with lumbosacral radicular pain secondary to disc herniation or degeneration. It found the transforaminal route more effective in reducing pain in the short term but not the long term, and no more effective for functional outcomes.

**Wei et al (2016)**

This SR compared transforaminal with interlaminar route injections for improving pain and functional outcomes in low back pain patients with lumbosacral radicular pain. It concluded that the transforaminal route had better pain relief outcomes in RCTs (n=9), but not in observational studies (n=4). However, there was no difference between the two approaches in terms of functional improvements, procedure frequency or rate of surgery.

**Evidence of effectiveness (in terms of pain relief and/or improved function) – key RCTs:**

Notable findings from the seven RCTs rated highest quality by the iCAHE reviewers include:

- A comparison of parasagittal interlaminar vs. transforaminal injections in 62 low back pain patients with lumbosacral radicular pain found that the two approaches were equivalent in terms of pain relief and functional improvement. The authors concluded that the parasagittal interlaminar approach may be considered a suitable alternative to the transforaminal approach given its equivalent effectiveness, technical ease and probably better safety profile (Ghai et al 2014).

- A 2015 RCT compared interlaminar and transforaminal epidural steroid injections with oral gabapentin in 145 patients with radiculopathy. There were no significant differences in pain scores at 1 or 3 months, but injection patients reported greater reductions in “worst leg pain” at one month (Cohen et al 2015).

**Evidence on safety:**

In addition to many of the SRs, a number of cohort studies and case series/case studies identified by the iCAHE reviewers reported evidence on safety and complications. Many of the complications associated with lumbar epidural steroid injections are similar across all three approaches and include:

- Minor (usually transient), e.g. headache, nausea, pain at injection site, increased sciatic pain
- Major (rare), e.g. dural puncture, epidural abscesses or haematomas, aseptic or bacterial meningitis, neurological injury, paraplegia

A 2012 SR of the evidence on transforaminal injections by Manchikanti et al (covered by the Shamliyan review) did not report any major complications and concluded that adverse events can be largely avoided by careful technique involving accurate needle placement, sterile precautions and a sound understanding of anatomy and fluoroscopic images. However the SR by Chien et al commented that transforaminal injections carry certain unique risks and that the potential for superior pain relief and functional outcomes needs to be balanced with an increased risk of complications.

The iCAHE reviewers concluded that there is moderate quality evidence that transforaminal injections are associated with a higher incidence of major complications than lumbar epidural steroid injections administered via alternative routes.
**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 reviewers found low quality evidence to suggest that lumbar epidural steroid injections in general (not specifically via the transforaminal route) may improve cost effectiveness outcomes in the short term through reducing sick days, the need for surgery and other health expenditure. However, the significance of any cost effectiveness benefits is dependent on the need for repeat injections.

In the ACC IPM service schedule, transforaminal injections of steroid with or without local anaesthetic are coded IN04. The unit cost is $873.39 exclusive of GST and the injections are always administered under imaging guidance. Over the last five years (2012 – 2016 inclusive) ACC has funded an average of 573 IN04 claims per year with annual costs of around $605,000.

**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.

Effectiveness:
- The evidence does not support the use of lumbar epidural steroids injections, via the transforaminal approach, for the first line relief of pain or improvement of disability in patients with radicular symptoms or low back pain (**Level B** based on moderate quality evidence from SRs/RCTs)
- The evidence suggests that the transforaminal approach is effective in reducing pain in patients with radiculopathy, particularly secondary to herniation of nucleus pulposus and particularly in the short term (**Level A** based on high quality evidence from SRs/RCTs)
- The evidence suggests that the transforaminal approach is not as effective in reducing disability and improving functional outcomes in patients with radiculopathy, particularly secondary to herniation of nucleus pulposus (**Level B** based on moderate to high quality evidence from SRs)
- The evidence suggests that the transforaminal approach is more effective in reducing pain due to radiculopathy compared to other lumbar epidural injection approaches (**Level B** based on moderate to high quality evidence from SRs)
- For radiculopathy of non-specific causes, the evidence suggests that the optimal approaches for reducing pain and improving functional outcomes are the transforaminal or interlaminar approaches in the short or long term (**Level B** based on moderate quality evidence from SRs/RCTs)
- For radiculopathy secondary to herniated disc the evidence suggests that the optimal approach for reducing pain and improving functional outcomes is the transforaminal approach in the short or long term. (**Level B** based on moderate to high quality evidence from SRs/RCTs)
- For pain due to a herniated disc, the evidence suggests that all approaches are equally effective in the short term for reducing pain and improving functional outcomes, with possibly slightly better long term outcomes from the transforaminal approach (**Level B** based on moderate quality evidence from a single SR)

Safety:
- Minor complications associated with lumbar epidural steroid injections are not uncommon, but rarely require significant medical attention (**Level B**)
- Major complications associated with lumbar epidural steroid injections are rare (**Level B**)
- Lumbar epidural steroid injections administered via the transforaminal route are associated with a higher incidence of major complications than other routes (**Level B**)

Cost effectiveness:
- The evidence suggests that lumbar epidural steroid injections may be cost effective in the short term through reducing sick days, the need for surgery and other health expenditure. Any significant cost effectiveness benefit is dependent on the need for repeat injections (**level C** based on evidence from cohort studies)
7. Purchasing recommendations

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

Taking recent evidence into account, PGAG advises that ACC adopts the following purchasing recommendations:

The evidence does not support the use of lumbar epidural steroid injections as a first line treatment for pain or disability in people with radicular symptoms or low back pain. However, the evidence suggests that lumbar epidural steroid injections using the transformaminal approach are effective for short (i.e. up to three months post treatment) and longer term relief of pain and improvement of function in people whose specific underlying pathology is radiculopathy secondary to a herniated disc.

Therefore:

- **Purchase transformaminal lumbar epidural steroid injections for clients with pain associated with a definitive diagnosis of radiculopathy secondary to disc herniation, supported by MRI investigation, to enable them to participate in appropriate multidisciplinary pain management programmes.**

- **If the pain persists, repeat injections may be considered after one year to enable further participation in pain management programmes.**

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

PGAG discussions

References


