

Key questions and background

Peripheral nerve ablation for the treatment of limb pain

Background

Clinical need and target population

Severe limb pain can markedly limit quality of life if it is not effectively managed. Chronic Limb pain can occur in a joint, such as the hip, shoulder or knee and is most often due to osteoarthritis.¹ Other causes of chronic limb pain include traumatic injury, rheumatoid arthritis, postoperative pain syndromes, or soft tissue (e.g., muscles, tendons, ligaments) dysfunction.² Standard treatments for chronic limb pain include physical activity, weight loss, medications (prescription drugs and over-the-counter pain relievers), physical therapy, complementary and alternative therapies (e.g., massage, acupuncture), and surgery.³ Treatments for osteoarthritis aim to reduce symptoms and improve function, although most treatments do not modify the natural history or progression of the disease.²

Technology of interest

Nerve ablation can be accomplished in several ways, including radiofrequency ablation, chemical ablation, and surgical ablation. There are three different types of radiofrequency ablation that have been developed. Standard thermal radiofrequency nerve ablation is a minimally invasive procedure that uses heat and coagulation necrosis to damage or destroy nerve tissue.² A high frequency electrical current is applied to the target tissue, using a needle electrode that is inserted through the skin.² The electrode generates heat (80 to 90°C) which coagulates a small volume of tissue.² The goal is to destroy peripheral sensory nerve endings, resulting in alleviation of pain.² However, the affected nerves may regenerate, causing the pain to return.⁴

Cooled radiofrequency is a newer technology that uses a water cooled radiofrequency probe to create a larger lesion size and therefore treat a larger area than standard thermal radiofrequency ablation.⁵ Cooled radiofrequency devices apply more energy at the desired location, but use water cooling to prevent as much heat diffusing beyond the target area.⁵ COOLIEF, produced by Haylard Health, Inc., is a cooled radiofrequency treatment that was cleared for marketing by the FDA in 2017.⁶ It is used to treat hip and knee osteoarthritis pain and is performed as an outpatient procedure.⁵

Pulsed radiofrequency treatment uses short bursts of radiofrequency current, rather than continuous current of standard radiofrequency ablation.² The heat from pulsed radiofrequency ablation (not exceeding 45°C) may cause less damage than standard thermal radiofrequency ablation.² Pulsed radiofrequency has been proposed as a possibly safer alternative to continuous radiofrequency ablation in the treatment of variety pain syndromes.²

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Policy context

Peripheral nerve ablation is one of many available treatments for patients with limb pain. This topic was selected for a health technology assessment because of high concerns for the safety and efficacy of the procedure and medium/high concern for cost.

This evidence review will help to inform Washington's independent Health Technology Clinical Committee as the committee determines coverage regarding peripheral nerve ablation for patients with limb pain.

Key questions

1. What is the evidence of efficacy and effectiveness for peripheral nerve ablation for limb pain compared to other active interventions, placebo, sham procedures, or no treatment?
2. What direct harms are associated with peripheral nerve ablation for limb pain compared to other active interventions, placebo, sham procedures, or no treatment?
3. Do important patient efficacy/effectiveness outcomes or direct harms from peripheral nerve ablation for limb pain vary by:
 - a. Indication
 - b. Patient characteristics
4. What are the cost-effectiveness and other economic outcomes of peripheral nerve ablation for limb pain compared to other active interventions, placebo, sham procedures, or no treatment?

Scope

Study component	Inclusion	Exclusion
Populations	Adults and children with chronic limb pain due to osteoarthritis or other conditions	Pain that does not arise from an extremity joint or soft tissue
Interventions	Peripheral nerve ablation using any technique	Ablation as part of another surgical intervention Procedures involving the central nervous system
Comparators	Other treatments for limb pain, including: <ul style="list-style-type: none"> • Medication • Surgery • Behavioral or psychological interventions • Physical therapy or other non-invasive non-medication therapies • Placebo 	Studies without a comparator intervention Studies with indirect comparisons Studies with an outdated comparator or a comparator

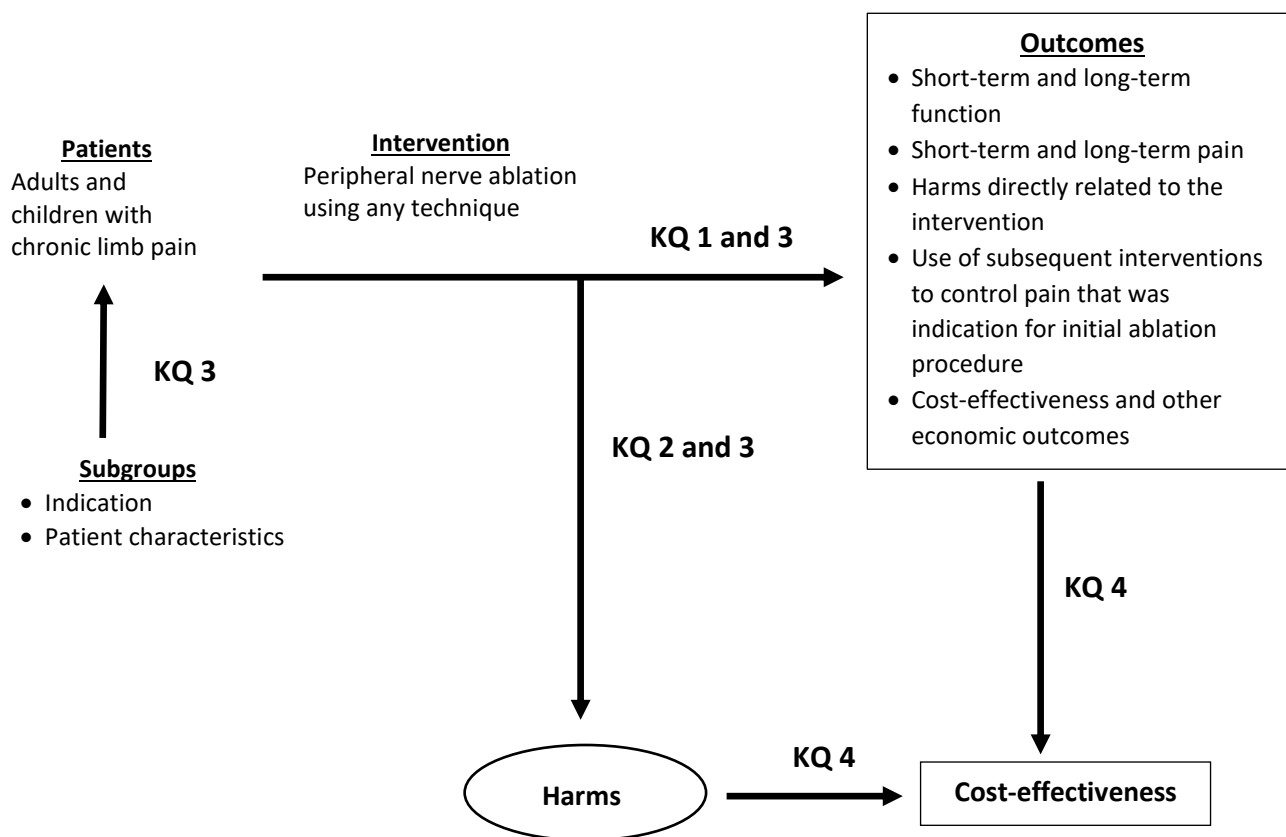
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Study component	Inclusion	Exclusion
	<ul style="list-style-type: none"> • Sham procedures • No treatment 	intervention that is not available in the U.S.
Outcomes	<ul style="list-style-type: none"> • Primary outcomes: short-term and long-term function measured by a validated method • Secondary outcomes: short-term and long-term pain measured by a validated method • Safety: harms directly related to the intervention • Indirect outcomes: use of subsequent interventions to control pain that was the original indication for the initial peripheral nerve ablation procedure • Economic: cost-effectiveness outcomes (e.g., cost per improved outcome) or cost-utility outcomes (e.g., cost per quality adjusted life year [QALY], incremental cost effectiveness ratio [ICER]) 	Other outcomes
Study design	<ul style="list-style-type: none"> • KQ 1–4 <ul style="list-style-type: none"> ○ Randomized controlled trials ○ Systematic reviews of randomized controlled trials • Additional studies/data for KQ 2–3 (harms) <ul style="list-style-type: none"> ○ Non-randomized comparative studies ○ Non-randomized studies without a comparator will be assessed for harms only, if evidence for the intervention is included in KQ1 ○ Governmental or other registries and databases containing reports of procedure-related harms or device recalls (e.g., FDA MAUDE database, FDA Medical Device Recall database) • Additional studies/data for KQ 4 <ul style="list-style-type: none"> ○ Cost-effectiveness studies and other formal comparative economic evaluations ○ Systematic reviews of cost-effectiveness studies and other formal comparative economic evaluations 	Abstracts, conference proceedings, posters, editorials, letters, case reports and case series with fewer than 10 subjects (for harms only), studies with harms outcomes for an intervention that is not included in KQ1

Study component	Inclusion	Exclusion
Publication	<ul style="list-style-type: none"> • Studies in peer reviewed journals, technology assessments or publically available FDA or other federal government reports • Published in English • Published from database inception through September 2018 	<p>Studies whose abstracts do not allow study characteristics to be determined</p> <p>Studies that cannot be located</p> <p>Duplicate publications of the same study that do not report different outcomes or follow-up times, or single site reports from multicenter studies</p> <ul style="list-style-type: none"> • Studies in languages other than English

Analytic framework

The analytic framework below will guide the selection, synthesis, and interpretation of available evidence.



Final

References

1. Centers for Disease Control and Prevention. Osteoarthritis (OA). 2017; <https://www.cdc.gov/arthritis/basics/osteoarthritis.htm>. Accessed 7/9/2018.
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4. Choi EJ, Choi YM, Jang EJ, Kim JY, Kim TK, Kim KH. Neural ablation and regeneration in pain practice. *Korean J Pain*. 2016;29(1):3-11.
5. Halyard Health Inc. COOLIEF cooled radiofrequency treatment. 2018; <https://www.mycoolief.com/>. Accessed 7/9/2018.
6. Halyard Health Inc. FDA clears Halyard Health's COOLIEF* for the management of osteoarthritis knee pain. 2017; <https://www.halyardhealth.com/about-us/halyard-news/2017/april/fda-clears-halyard-healths-coolief-for-the-management-of-osteoarthritis-knee-pain.aspx>. Accessed 7/9/2018.

Public comment and response

See **Draft key questions: Comment and response** document published separately.