Washington State Health Care Authority

Draft key questions and background

Extracorporeal shock wave therapy (ESWT) for musculoskeletal conditions

Public comments on the draft key questions accepted: August 12, to August 25, 2016.

Background

Originally developed to treat kidney stones and gallstones, extracorporeal shock wave therapy (ESWT) has been used for more than two decades to treat an increasing number of musculoskeletal conditions, such as tennis elbow, rotator cuff tendinitis, patellar tendinopathy, Achilles tendinopathy, plantar fasciitis, and bony non-unions. ESWT is a procedure in which a series of high- or low-energy shockwaves are directed at the site of injury, and is commonly used in patients who have not responded to more conservative treatment modalities. Although the exact mechanism by which ESWT elicits a therapeutic effect is not fully understood, it is thought that ESWT induces tissue regeneration and neovascularization, induces pain relief via hyperstimulation analgesia, and in the case of tendinopathies, disintegrates calcified deposits.

ESWT devices have received FDA-approval for lateral epicondylitis and plantar fasciitis. ESWT devices employ either focused shockwaves or radial pressure waves. Focused shockwaves are high energy acoustic waves that converge to achieve maximal energy at the target site – the energy of focused shockwaves is not diminished upon skin penetration. Focused shockwaves are generated in water via electrohydraulic, electromagenetic, or piezoelectric techniques. In contrast, radial shockwaves (or radial pressure waves) diverge as soon as they are discharged – the energy of radial pressure waves diminish upon skin penetration and result in low energy diffuse waves at the target site. Radial pressure waves are generated by pneumatic techniques. While radial ESWT is newer to the market, focused ESWT has been in use for many years and appears to be able to direct higher energy shockwaves at deeper tissue sites. The therapeutic impact of focused versus radial ESWT remains unclear, as the relationship between shockwave characteristics and mechanism of action has not been elucidated.

Although ESWT is increasingly being used to treat a variety of musculoskeletal conditions, the efficacy and safety of this procedure remain unclear. The objective of this report is to systematically review and critically appraise the evidence of the comparative efficacy, effectiveness, and safety of ESWT for the treatment of musculoskeletal conditions such as tendinopathies and plantar fasciitis. The differential effectiveness and safety of ESWT for subpopulations will be evaluated, as will the cost effectiveness.

Policy context/Reason for selection: Extracorporeal shock wave therapy (ESWT) is a noninvasive treatment based on ultrasound technology. ESWT is used for a variety of conditions including treatment of kidney stones. ESWT for soft tissue injuries is applied with the goal of promoting healing. ESWT may have multiple effects thought to impact healing including breaking calcium deposits and causing an inflammatory response that may stimulate tissue healing. The concern for the efficacy and safety of ESWT are high, while the concern regarding cost is medium/high.

Policy context

Extracorporeal shock wave therapy (ESWT) is a noninvasive treatment based on ultrasound technology. ESWT is used for a variety of conditions including treatment of kidney stones. ESWT for soft tissue injuries is applied with the goal of promoting healing. ESWT may have multiple effects thought to impact healing including breaking calcium deposits and causing an inflammatory response that may stimulate tissue healing.

Scope

Population: Patients with tendinopathy or tendinitis, plantar fasciitis, heel spurs, subacromial shoulder pain, or osteoarthritis. (Kidney stones; gallstones; cutaneous wounds; muscle spasticity; as well as dental, cosmetic, cardiovascular, and neurological conditions will be excluded).

Intervention: ESWT. (ESWT used in conjunction with surgery will be excluded.)

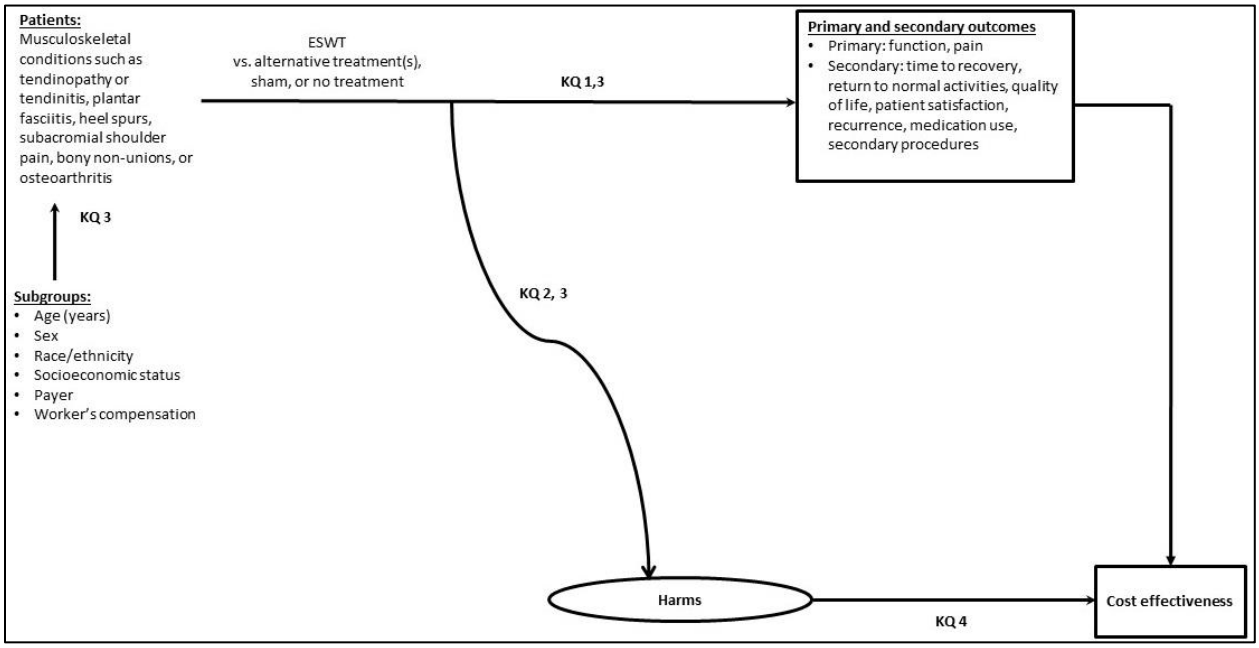
Comparators: Alternative treatment(s), sham, or no treatment. (Comparisons of ESWT such as different modalities (e.g., radial vs. focused ESWT, high- vs. low-energy ESWT) will be excluded.)

Outcomes: Function (primary), pain (primary), time to recovery, return to normal activities (sports, work, or activity level), quality of life, patient satisfaction, recurrence, medication use, secondary procedures (e.g., surgery), adverse events (primary), cost-effectiveness (e.g., cost per improved outcome), cost-utility (e.g., cost per quality adjusted life year (QALY), incremental cost effectiveness ratio (ICER) outcomes.

Draft key questions

In patients with musculoskeletal conditions such as tendinopathy, plantar fasciitis, heel spurs, subacromial shoulder pain, or osteoarthritis:

1. What is the evidence of the short- and long-term efficacy and effectiveness of ESWT compared with alternative treatment options, sham, or no treatment?
2. What is the evidence regarding short- and long-term harms and complications of ESWT compared with alternative treatment options, sham, or no treatment?
3. Is there evidence of differential efficacy, effectiveness, or safety of ESWT compared with alternative treatment options, sham, or no treatment? Include consideration of age, sex, race, ethnicity, socioeconomic status, payer, and worker's compensation?
4. What is the evidence of cost-effectiveness of ESWT compared with alternative treatment options or no treatment?



Public comment and response

Submit comments to the HTA program at shtap@hca.wa.gov .

For additional information on key questions and public comment.