Washington State Health Care Authority

FINAL key questions and background

Extracorporeal shock wave therapy (ESWT) for musculoskeletal conditions

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 noninvasive 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. The term extracorporeal shockwave therapy has sometimes been used to describe treatment delivered by two different types of devices. One emits focused *shock* waves, the other emits 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. Radial "extracorporeal shock wave therapy" is a misnomer; it is considered a pressure wave technology as it does not produce a shockwave. It will be excluded from this review. Focused ESWT has been in use for many years and appears to be able to direct high energy shockwaves at deeper tissue sites. The therapeutic impact of focused ESWT remains unclear, as the relationship between shockwave characteristics and mechanism of action has not been elucidated.

Although focused 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

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.

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, bony non-unions, fractures, carpal tunnel syndrome, shin splints, greater trochanteric pain syndrome, coccydynia, Dupuytren's disease, myofacscial pain, cardiovascular, osteonecrosis, postoperative patients and neurological conditions will be excluded).

Intervention: Focused ESWT (ESWT used in conjunction with surgery and radial extracorporeal shockwave therapy will be excluded.)

Comparators: Standard 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.)

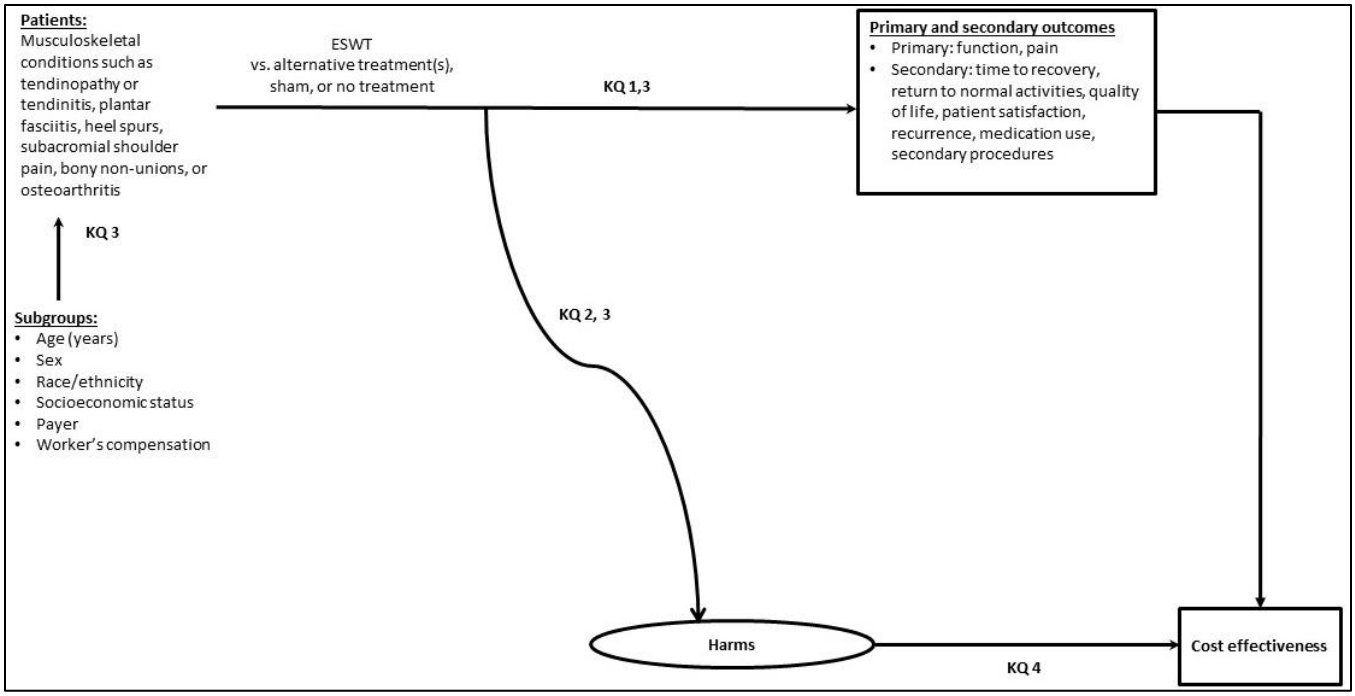
Outcomes: Function (primary), pain (primary), adverse events (primary), quality of life, patient satisfaction, medication use, surgery, cost-effectiveness (e.g., cost per improved outcome), cost-utility (e.g., cost per quality adjusted life year (QALY), incremental cost effectiveness ratio (ICER) outcomes.

Studies: Focus will be on studies with the least potential for bias such as high quality systematic reviews of randomized controlled trials and randomized controlled trials and full economic studies.

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 focused ESWT compared with standard alternative treatment options, sham, or no treatment?
2. What is the evidence regarding short- and long-term harms and complications of focused ESWT compared with standard alternative treatment options, sham, or no treatment?
3. Is there evidence of differential efficacy, effectiveness, or safety of focused ESWT compared with standard 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 focused ESWT compared with standard alternative treatment options or no treatment?



Public Comment & Response

See ***Draft Key Questions: Public Comment & Response*** document published separately.