

# Effect of extracorporeal shock wave for tennis elbow

## A protocol for systematic review of randomized controlled trial

Hua-yu Tang, MM<sup>a</sup>, Tao Yu, MM<sup>a</sup>, Wei Wei, MM<sup>a</sup>, Yu Zhao, MB<sup>b,\*</sup>

### Abstract

**Background:** Previous clinical studies have reported that extracorporeal shock wave (EPSW) is an effective treatment for patients with tennis elbow (TE). However, no systematic review has assessed its effectiveness and safety for the treatment of TE.

**Methods:** In this systematic review, we will search the potential eligible literature from the following electronic databases: Central, Embase, MEDLINE, CINAHL, and CNKI from inception to the present. All literatures of randomized controlled trials of EPSW for TE will be considered without language restrictions. Two reviewers will independently select the studies, extract the data, and evaluate the methodology quality. All disagreements between those 2 reviewers will be resolved by a third reviewer involved through discussion. Outcome data will be pooled by RevMan 5.3 software if the heterogeneity is reasonable. Reporting bias will also be conducted if more than 10 included studies can be reached.

**Results:** This systematic review will evaluate the clinical effectiveness and safety of EPSW for TE.

**Conclusion:** The findings of this study will summarize the current evidence of EPSW on TE outcomes and may provide guidance for both clinical practice and further studies.

**Dissemination and ethics:** This systematic review does not need ethical approval, because it does not utilize the individual patient data. Its findings are expected to publish in peer-reviewed journals.

**Systematic review registration:** PROSPERO CRD42019119687.

**Abbreviations:** CIs = confidence intervals, EPSW = extracorporeal shock wave, RCT = randomized controlled trial, TE = tennis elbow.

**Keywords:** effectiveness, extracorporeal shock wave, safety, stroke, systematic review, tennis elbow

## 1. Introduction

Tennis elbow (TE) is a common condition among general population.<sup>[1–3]</sup> It often manifests as elbow pain, swelling or tenderness.<sup>[4–6]</sup> It has been reported that its incidence is about 4 to 7 subjects per 1000 people annually.<sup>[7–9]</sup> Further study reported that about 1% to 3% subjects experience this disorder over the course of their lifetime, and mostly affects individuals between 35 and 50 years old.<sup>[10]</sup> If this condition cannot be managed timely and effectively, it can greatly affect the quality of life in subjects with TE.

*This study is partly supported by the Heilongjiang Provincial Health and Family Planning Research Project (2018-300). The supported institute will not involve in the whole process of this study.*

*The authors have no conflicts of interest to disclose.*

<sup>a</sup> Second Ward of Orthopedics Department, First Affiliated Hospital of Jiamusi University, Jiamusi, <sup>b</sup> Department of Orthopedics, Huludao Central Hospital, Huludao, China.

\* Correspondence: Yu Zhao, Department of Orthopedics, Huludao Central Hospital, No. 15 Lianshan Street, Lianshan District, Huludao, 125001, China (e-mail: Yuzhao2001@outlook.com).

Copyright © 2019 the Author(s). Published by Wolters Kluwer Health, Inc. This is an open access article distributed under the Creative Commons Attribution License 4.0 (CCBY), which permits unrestricted use, distribution, and reproduction in any medium, provided the original work is properly cited.

Medicine (2019) 98:7(e14517)

Received: 22 January 2019 / Accepted: 23 January 2019

<http://dx.doi.org/10.1097/MD.00000000000014517>

Several managements are used to treat this condition, including medications, activity modification, physical therapy, as well as the local corticosteroid injection.<sup>[11–14]</sup> However, many subjects still report a low recovery rate achieved after the treatment.<sup>[11,12]</sup> Therefore, additional alternative therapies are still needed to treat this condition.

Fortunately, a variety of studies reported that alternative therapy, such as acupuncture, extracorporeal shock wave (EPSW) is effective for the management of TE, especially for EPSW.<sup>[15–20]</sup> However, no systematic review has been conducted to assess the effectiveness and safety of EPSW for patients with TE. Thus, the protocol of present systematic review and meta-analysis will focus on evaluating the effectiveness and safety of EPSW for TE.

## 2. Methods

### 2.1. Objectives

The aim of this systematic review is to assess the effectiveness and safety of EPSW for TE.

### 2.2. Study registration

The protocol of this systematic review has been registered on <http://www.crd.york.ac.uk/PROSPERO> with CRD42019119687. It is designed and reported based on the Preferred Reporting Items for Systematic Reviews and Meta-Analysis Protocol statement guidelines.<sup>[21]</sup>

### 2.3. Inclusion criteria for study selection

**2.3.1. Type of study.** Only randomized controlled trial (RCT) of EPSW for TE will be considered for inclusion. Other studies, such as non-RCT, quasi-RCT, case-control study, case reports, case series, and nonclinical studies will not be considered.

**2.3.2. Type of participants.** Participants clinically diagnosed of TE will be included regardless of their gender, age, and race. However, patients will be excluded if TE resulted from other disorders, such as previous elbow surgery, and trauma.

**2.3.3. Type of interventions.** Any RCTs for assessing the effectiveness and safety of EPSW for TE will be included. However, the studies involved the combination of EPSW with other treatments will not be considered. The control treatments will consist of any other interventions that will not include any types of EPSW intervention.

**2.3.4. Type of outcome measurements.** Primary outcome includes elbow pain intensity. It will be measured by any pain measurement tools, such as visual analog scale or numeric Rating Scale, and any others. Secondary outcomes consist of elbow function, as assessed by related scales, including Mayo Elbow Performance Score, American Shoulder and Elbow Surgeons Elbow scores, and abbreviated Disability of the Shoulder and Hand score; quality of life, as evaluated by 36-Item Short Form Health Survey, and any other associated scales; as well as any adverse events.

### 2.4. Search methods for the identification of studies

**2.4.1. Electronic searches.** The following databases will be retrieved from inception to the present, including Cochrane Central Register of Controlled Trials, Embase, MEDLINE, Cumulative Index to Nursing and Allied Health Literature, and China National Knowledge Infrastructure. The details of search strategy for MEDLINE are shown in Table 1. The equivalent strategies will be applied for other databases, and will be also translated into Chinese while searching the Chinese database.

**2.4.2. Search for other resources.** Additionally, website of clinical registry, dissertations, as well as the reference lists of all

included studies will also be searched to avoid missing any potential eligible studies.

### 2.5. Data collection and analysis

**2.5.1. Study selection.** Two reviewers will independently screen the titles, abstracts, as well as full texts according to the predefined criteria. All select procedures will be performed based on the PRISMA flowchart. Any oppositions regarding the study selection occurred between 2 reviewers will be resolved by a third reviewer through discussion. The process of study selection is shown in Figure 1.

**2.5.2. Data extraction and management.** Two reviewers will also independently extract data from each included study by using a predefined standard data extraction form. It includes detailed information of title, first author, published data, region, study design, study methods, such as the procedures of randomization, allocation, and blinding, outcome measurements, and any other details. Any divergences will be handled by a third reviewer through discussion.

**2.5.3. Risk of bias assessment.** Cochrane tool of risk of bias will be utilized to evaluate the risk of bias for each included study by 2 independent reviewers. Each study will be assessed on 7 domains, and each item will be presented as a high risk of bias, unclear risk of bias, or low risk of bias. Any differences of risk of bias evaluation will be dealt with a third reviewer through discussion.

**2.5.4. Measurement of treatment effect.** The continuous data will be presented as the mean difference, or standardized mean difference with 95% confidence intervals (CIs). The dichotomous data will be presented as the risk ratio with 95% CIs. If ordinal data are available only, they will be converted to dichotomous data.

**2.5.5. Missing data management.** For any insufficient, unclear or even missing data, we will contact the original corresponding authors to request those data. If those additional data cannot be achieved, the current available data will be pooled and analyzed, and it will be discussed in Section 3.

**2.5.6. Assessment of heterogeneity.** The tests of  $I^2$  and  $\chi^2$  will be utilized to detect the heterogeneity. A fair and reasonable heterogeneity is defined as the value of  $I^2 \leq 50\%$ . Otherwise, it will be regarded as having substantial heterogeneity.

**2.5.7. Data synthesis.** If the  $I^2 \leq 50\%$ , the outcome data will be pooled by using fixed-effect model, and a meta-analysis will be carried out. Otherwise, the random-effect model will be used. Meanwhile, subgroup analysis will be conducted to identify any possible factors that may cause such situation. If the heterogeneity is still significant post the subgroup analysis, the data will not be pooled and a meta-analysis will not be performed. However, a narrative summary will be presented instead.

**2.5.8. Subgroup analysis.** If substantial heterogeneity is identified, subgroup analysis will be conducted based on the different forms of treatments, controls, and outcomes.

**2.5.9. Sensitivity analysis.** If it is possible, we will also conduct sensitivity analysis to check the robustness of the pooled results according to the methodological qualities, and statistical models.

**2.5.10. Publication biases.** If more than 10 eligible studies will be included, funnel plot will be performed to detect the potential

**Table 1**

**Search strategy applied in MEDLINE database.**

Number	Search terms
1	Tennis elbow
2	Tennis
3	Elbow
4	Lateral epicondylitis
5	Lateral
6	Epicondylitis
7	Or/1-6
8	Randomized controlled trial
9	Controlled clinical trial
10	Randomly
11	Randomized
12	Trial
13	Or/8-12
14	Extracorporeal shock wave
15	Extracorporeal
16	Shock
17	Wave
18	Or/14-17
19	7 and 13 and 18

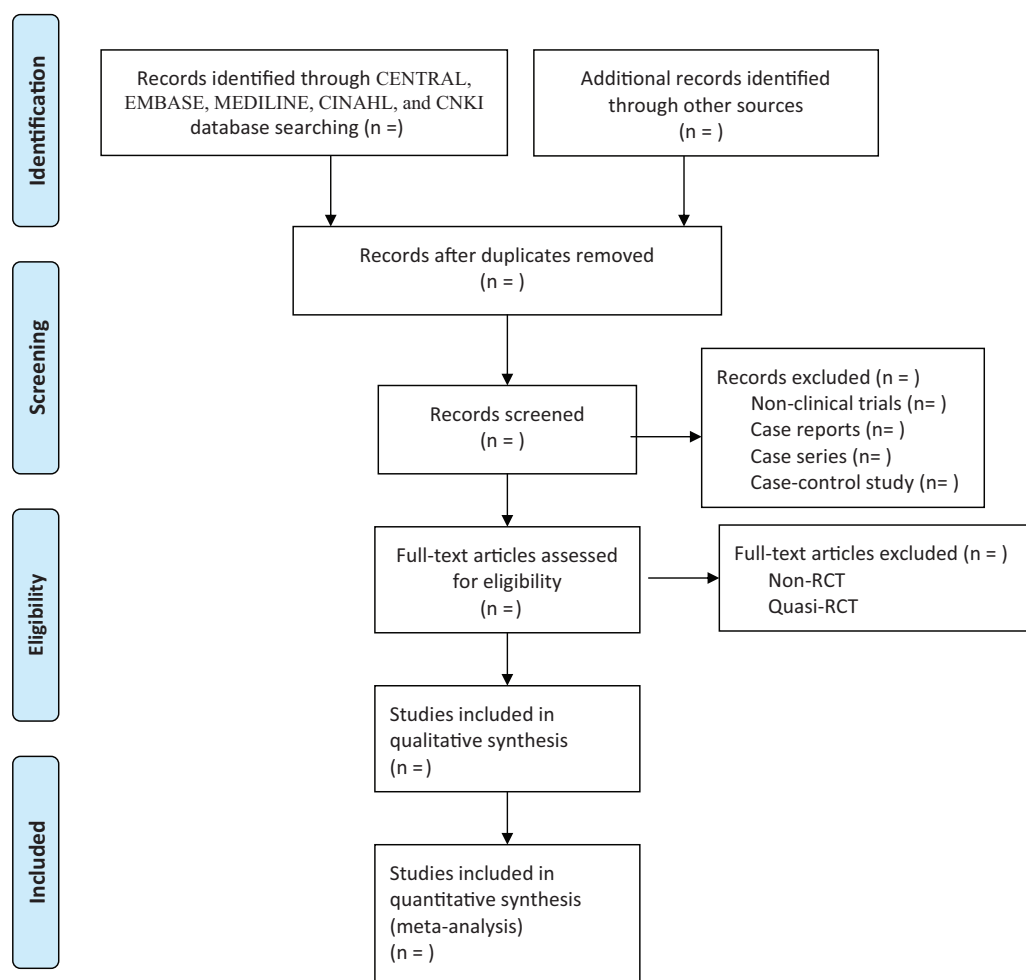


Figure 1. Process of study selection.

publication biases.<sup>[22]</sup> In addition, Egg's and Begg's tests will be conducted to identify that if the funnel plot is asymmetry.<sup>[23]</sup>

### 3. Discussion

TE is gravely tormenting individuals and greatly reduces the quality of life in patients who experience it. EPSW is a nonpharmaceutical therapy that is reported to treat TE effectively. However, no systematic review has been conducted to assess the effectiveness and safety of EPSW for the treatment of TE. Thus, this systematic review will firstly explore this issue.

In the current systematic review, we will retrieve all associated and potential eligible studies without language restrictions. All studies related to the EPSW for the treatment of TE will be fully considered. The results of this systematic review will present a summary of the updated evidence on the effectiveness and safety of EPSW for patients with TE. It may also provide helpful evidence for the clinical practice and even the health policy-makers.

#### Author contributions

**Conceptualization:** Tao Yu, Yu Zhao.

**Data curation:** Hua-yu Tang, Tao Yu, Wei Wei, Yu Zhao.

**Formal analysis:** Tao Yu, Wei Wei.

**Investigation:** Hua-yu Tang.

**Methodology:** Tao Yu, Wei Wei, Yu Zhao.

**Project administration:** Hua-yu Tang.

**Resources:** Tao Yu, Wei Wei, Yu Zhao.

**Software:** Tao Yu, Wei Wei.

**Supervision:** Hua-yu Tang.

**Validation:** Hua-yu Tang, Tao Yu, Yu Zhao.

**Visualization:** Hua-yu Tang, Tao Yu, Yu Zhao.

**Writing – original draft:** Hua-yu Tang, Tao Yu, Wei Wei, Yu Zhao.

**Writing – review & editing:** Hua-yu Tang, Wei Wei, Yu Zhao.

#### References

- [1] Pierce TP, Issa K, Gilbert BT, et al. A systematic review of tennis elbow surgery: open versus arthroscopic versus percutaneous release of the common extensor origin. *Arthroscopy* 2017;33:1260–8.
- [2] Taylor SA. Evaluation and management of elbow tendinopathy. *Sports Health* 2012;4:384–93.
- [3] Orchard J, Kountouris A. The management of tennis elbow. *BMJ* 2011;342:d2687.
- [4] Bisset L, Coombes B, Vicenzino B. Tennis elbow. *BMJ Clin Evid* 2011;2011:
- [5] Mallen CD, Chesterton LS, Hay EM. Tennis elbow. *Praxis (Bern 1994)* 2010;99:309–10.
- [6] Buchbinder R, Green SE, Struijs P. Tennis elbow. *BMJ Clin Evid* 2008;2008:1117.

- [7] Chard MD, Hazleman BL. Tennis elbow—a reappraisal. *Br J Rheumatol* 1989;28:186–90.
- [8] Hamilton PG. The prevalence of humeral epicondylitis: a survey in general practice. *J R Coll Gen Pract* 1986;36:464–5.
- [9] Kivi P. The etiology and conservative treatment of humeral epicondylitis. *Scand J Rehabil Med* 1983;15:37–41.
- [10] Nirschl RP, Ashman ES. Elbow tendinopathy: tennis elbow. *Clin Sports Med* 2003;22:813–36.
- [11] Branson R, Naidu K, du Toit C, et al. Comparison of corticosteroid, autologous blood or sclerosant injections for chronic tennis elbow. *J Sci Med Sport* 2017;20:528–33.
- [12] Matache BA, Berdusco R, Momoli F, et al. A randomized, double-blind sham-controlled trial on the efficacy of arthroscopic tennis elbow release for the management of chronic lateral epicondylitis. *BMC Musculoskelet Disord* 2016;17:239.
- [13] Ozden R, Uruç V, Doğramaci Y, et al. Management of tennis elbow with topical glyceryl trinitrate. *Acta Orthop Traumatol Turc* 2014;48:175–80.
- [14] Peterson M, Butler S, Eriksson M, et al. A randomized controlled trial of exercise versus wait-list in chronic tennis elbow (lateral epicondylitis). *Ups J Med Sci* 2011;116:269–79.
- [15] Su X, Wu ZQ, Cao XM. Effects of electroacupuncture of different frequencies for treatment of patients with refractory tennis elbow syndrome. *Zhongguo Zhen Jiu* 2010;30:43–5.
- [16] Shin KM, Kim JH, Lee S, et al. Acupuncture for lateral epicondylitis (tennis elbow): study protocol for a randomized, practitioner-assessor blinded, controlled pilot clinical trial. *Trials* 2013;14:174.
- [17] Lizis P. Analgesic effect of extracorporeal shock wave therapy versus ultrasound therapy in chronic tennis elbow. *J Phys Ther Sci* 2015;27:2563–7.
- [18] Staples MP, Forbes A, Ptasznik R, et al. A randomized controlled trial of extracorporeal shock wave therapy for lateral epicondylitis (tennis elbow). *J Rheumatol* 2008;35:2038–46.
- [19] Ho C. Extracorporeal shock wave treatment for chronic lateral epicondylitis (tennis elbow). *Issues Emerg Health Technol* 2007;96:1–4.
- [20] Melikyan EY, Shahin E, Miles J, et al. Extracorporeal shock-wave treatment for tennis elbow. A randomised double-blind study. *J Bone Joint Surg Br* 2003;85:852–5.
- [21] Shamseer L, Moher D, Clarke M, et al. PRISMA-P Group Preferred reporting items for systematic review and meta-analysis protocols (PRISMA-P) 2015: elaboration and explanation. *BMJ* 2015;349:g7647.
- [22] Higgins JPT, Green S. The Cochrane Collaboration Cochrane Handbook for Systematic Reviews of Interventions Version 5.1.0 [updated March 2011]. 2011; Available at: <http://www.cochrane-handbook.org>.
- [23] Egger M, Davey Smith G, Schneider M, et al. Bias in meta-analysis detected by a simple, graphical test. *BMJ* 1997;315:629–34.