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Effect of Extracorporeal Shock Wave Therapy on Pain in Diabetic Patients with Frozen Shoulder: A Meta-Analysis Protocol

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Protocol; ESWT; Diabetes; Frozen shoulder; Pain score; Motor function

1. Abstract

Diabetes is a significant risk factor for shoulder mobility problems, according to a considerable body of clinical study evidence to date. As a new treatment method for frozen shoulder, Extracorporeal shock-wave therapy (ESWT) has been developed. Its efficacy and safety have been clinically confirmed, but its efficacy in the treatment of patients with adhesive periarthritis of shoulder combined with diabetes is rarely reported. The purpose of our study was to systematically review the efficacy and safety of extracorporeal shock wave therapy in patients with adhesive periarthritis of shoulder combined with diabetes.

2. Method and Analysis

Systematic searches will be conducted by MEDLINE, EMBASE, CINAHL, Physiotherapy Evidence Database (PEDro), Cochrane Central Register of Controlled Trials (CENTRAL), PsycINFO, Chinese Biomedical Literature Database (CBM), WANFANG database, China National Knowledge Infrastructure (CNKI), Chinese Scientific Journal Database (VIP), and all relevant English articles will be reviewed from the establishment of the database until March 2023.

3. Introduction

Frozen shoulder (FS), also known as adhesive capsulitis, is a common shoulder disorder that presents with pain and progressive loss of shoulder movement [1]. It can be either primary or secondary, which means whether the condition occurs spontaneously with no known cause or trauma (primary FS), or is related to trauma, surgery, or other pathology, such as subacromial pain (secondary FS). FS has been related to a range of risk factors, including cardiovascular disease, parkinson disease, hyperthyroidism stroke and, in particular, diabetes mellitus. [2] hypothyroidism, hyperlipidaemia and autoimmune diseases are also associated with FS. In addition, radical neck dissection, acute cerebrovascular aneurysm surgery and subarachnoid haemorrhage and in individuals with Parkinson disease result in shoulder pain and dysfunction. Particularly, the incidence of FS can reach close to 60% in diabetes mellitus. A dialong shoulder study has the prevalence of musculoskeletal disorders and associated pain, stiffness, and disability in patients with type 1 diabetes (DM1) over 45 years compared to controls in a cross-sectional study. They found that in the DM1 group, the point prevalence of periarthritis of shoulder was 59 percent and the lifetime prevalence was 76 percent [3]. Besides, an analytical observational study of frozen shoulder among patients with diabetes mellitus reveals the prevalence of FS among diabetic patients and its relation to demographic features [4]. There is much evidence that diabetes effects on muscle tissues, joint, and connective tissue, Little is known about the causal relationship between diabetes and musculoskeletal dysfunction. It is believed that the formation of advanced glycation end products (AGEs) in diabetes mellitus may also affect collagen tissues and chondrocytes through various mechanisms [5]. Frozen shoulders are initially treated with conservative (non-surgical) methods, including analgesics, local corticosteroid injections, and mild activity and exercise. Manual release under anesthesia, arthroscopic capsularrelease, or arthroscopic dilatation/hydrodilatation can be attempted when above-mentioned conservative methods are noneffective. While, there is no clear consensus on which treatment strategy is the most effective method for the treatment of FS. Although the use of

hormones significantly improved symptoms across the board, complications it brings cannot be ignored. It impacts blood glucose, especially in FS with diabetes, which appears to be particularly important [7]. Invasive therapeutic regimens improve symptoms

in short term, but there is no obvious benefits in long turn [8-9]. At present, extracorporeal shock wave therapy (ESWT), as a new treatment method, has been widely concerned. ESWT is a pulsed sound wave with short duration, high pressure amplitude, and relatively low tensile wave component. It has been used in a variety of soft tissue diseases, including lateral epicondylitis, plantar fasciitis and shoulder calcifying tendinitis. ESWT stimulates soft tissue healing, increases blood flow to the treated site, and induces an inflammatory mediated healing process. In addition, ESWT has been successfully used in the treatment of Dupuytren's contracture. Due to the similar pathogenesis of Dupuytren's contracture and shoulder adhesive bursitis, ESWT is currently used in the treatment of FS. Up to now, ESWT has shown good ability to improve range of motion, pain relief, and high security [10-12]. There is no clear evidence on extracorporeal shock wave therapy for diabetic patients with FS, but existing researches show that ESWT is resultful in FS with diabetes mellitus [13]. In 2022, a study on the efficacy of extracorporeal shock wave therapy at different energy levels in patients with frozen shoulder combined with diabetes showed that both high and low doses of shock wave therapy were effective in these patients [16]. However, there are no large-scale clinical trials to demonstrate the exact clinical efficacy of extracorporeal shock wave therapy in patients with diabetes mellitus combined with frozen shoulder. This study compared the therapeutic effect of extracorporeal shock wave therapy on diabetic patients with FS and non-diabetic patients with FS, so as to solve the key questions of whether extracorporeal shock wave therapy on diabetic patients with FS has the same efficacy and safety as that on diabetic patients with FS.

4. Methods

4.1. Study Registration

The study program runs from November 1, 2022 to November 1, 2022. This protocol was developed in accordance with the Preferred Reporting Project for Systematic Review and Meta-Analysis (PRISMA) program. The final systematic review will follow the guidelines of the PRISMA Statement and the Cochrane Manual for Systematic Review of Interventions.

4.2. Inclusion Criteria for Study Selection

If the inclusion criteria for PICO elements (p= participant, I= intervention, C= comparison, O= outcome) and study type definitions are met, the final evaluation is included Studies will be included in final review if they meet the following inclusion criteria: Participants were clinically diagnosed patients with FS combined with diabetes. Patients with pre-onset FS trauma, stroke, cervical disc disease, heart disease, thyroid dysfunction, dyslipidemia, Parkinson's disease, Dupuytren's contracture, genetic factors, hypertension and other underlying diseases would be excluded. There are no restrictions on the race or nationality of participants.

4.3. Types of Interventions

Only extracorporeal shock waves, including divergent and focused, are not limited by treatment time, frequency, or intensity.

4.4. Types of Outcome Measures

1.ROM: While the clear way to describe shoulder motion in 3D is to describe it in terms of elevation and elevation, many studies describe them in terms of flexion and extension and abduction and adduction. This is still the most commonly used description in clinical practice, so all reported shoulder movements have been translated into the latter term in this review. The elevation Angle of PoE≤-45° is converted according to the shoulder extension. Similarly, PoE elevation angles between 45° and 135°, between -45 ° and 45°, and >135° are translated according to shoulder flexion,

abduction, or adduction, respectively. Data extraction of participant characteristics (number of participants, sex, age), methods (tracking system, upper extremity assessment), and mean (standard deviation if reported in tabular or text form) shoulder flexion, shoulder extension, abduction and adduction, elbow flexion and extension joint angles were performed by one reviewer to extract graphically reported joint angles as accurately as possible, with graphs enlarged if necessary. A second examiner verified the extracted data.[14]

2.VAS: The pain VAS is a continuous scale consisting of horizontal (HVAS) or vertical (VVAS) lines, typically 10 cm (100 mm) in length, fixed by 2 verbal descriptors, each corresponding to an extreme symptom [13]

4.5. Search Strategy

Search methods for the identification of studies:The following key electronic bibliographic databases will be searched from inception to March 2023: MEDLINE,EMBASE,CINAHL,Cochrane Central Register of Controlled Trials (CENTRAL),Physiotherapy-EvidenceDatabase(PEDro),PsycINFO,Chinese Biomedical Literature Database (CBM),China National Knowledge Infrastructure (CNKI),WANFANG atabase,Chinese Scientific Journal Database (VIP).To construct the search, the Patient, Intervention, Comparison, Outcome, Study scheme will be used, the search strategy will search for 'ESWT' AND 'diabetes' AND 'frozen shoulder'.

5. Data Collection

5.1. Study Selection

The retrieved records were imported into bibliographic software EndNote V.X. 9. Identify and remove any duplicate records using EndNote. The two review authors will independently screen the titles, abstracts, and keywords of the remaining articles according to pre-set criteria. After the initial screening, two review authors independently conduct a detailed review to retrieve the full text of all potentially eligible articles. Excluding unqualified studies, a clear reason for their exclusion will

be recorded. Differences arising from the process will be resolved through discussion or consultation with the third author. (Figure 1) is a flow diagram of the selection process.

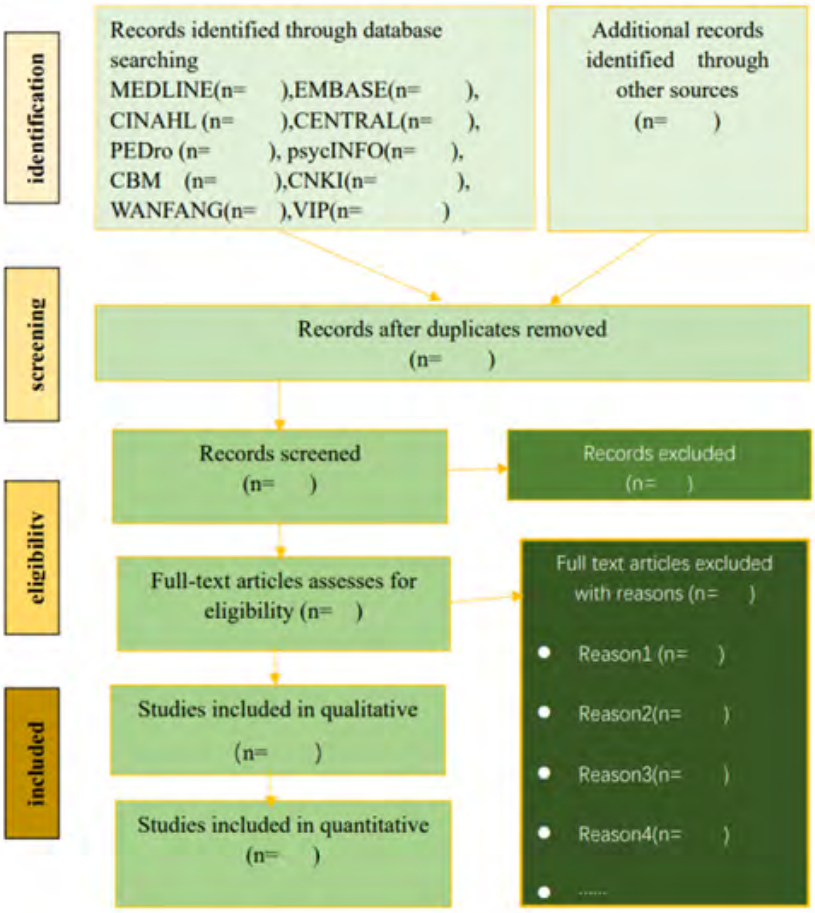

Figure 1: A flow diagram of the selection process

5.2. Data Extraction and Management

The two review authors will independently extract the following data from the included studies using a pre-designed data collection Excel sheet:

➢ General information: article title, journal, year of publication, first author, corresponding author, country of study, purpose of the study, trial registration, source of research funding, and possible conflicts of interest.

➢ Study characteristics: study design, randomisation method, blinding method, allocation concealment and completeness of outcome data.

➢ Participants: sample size, baseline participant characteristics.

➢ Interventions: type, frequency, intensity and duration.

➢ Outcomes: Outcome measures, reporting time point, follow-up time, and adverse events.

5.3. Data Analysis and Synthesis

Meta-analysis was performed using Cochrane Review Manager V.5 to meta-analyze the effects of our study. If at least two studies use the same outcome measurement method or measure similar structures, a tele-rehabilitation program will be conducted. The summary results are calculated in different ways depending on the data type. For continuous data, standardized mean difference as and 95% ci are calculated. For binary data, or and 95% ci are calculated. The $\chi 2$ test and I2 statistic were used to assess the heterogeneity of each study. If $p>0.1$ and I2 <50%, the fixed effects model is used for data consolidation. If $p>0.1$ and $I2 \geq 50\%$, the random-effects model was used to combine the data, considering the significant heterogeneity between studies. If $p \leq 0.1$, statistical significance was considered and subgroup analysis or narrative description was performed. A narrative description will synthesize the findings of multiple studies, primarily using text and text to summarize and explain the findings from the included studies. Pre-designated groupings based on gender will be established when sufficient data are available; Complications; the type, frequency, intensity and duration of telerehabilitation programmes; and staging of frozen shoulder arthritis to explore factors that may be related to the strength of the influence around the shoulder. If the data allows, a sensitivity analysis is performed to check the robustness and reliability of the results by omitting specific tests from the overall analysis. If more than 10 trials were included in the meta-analysis, we constructed funnel plots to explore potential publication bias. The overall quality of each pooled evidence will be assessed using the recommended graded assessment, development and evaluation system, graded into four levels: high, medium, low or very low. Two review authors will independently assess the certainty of the evidence using GRADEpro software

(https:// gradepro.org), and possible discrepancies will be resolved by discussion or consultation with third authors.

5.4. Patient and Public Involvement

This systematic review protocol does not directly involve patients or the public. Data will be collected from published articles retrieved from primary databases and manually searched

5.5. Ethics and Dissemination

No ethical approval is required for this review. The final results will be published in a peer-reviewed journal.

6. Discussion

The pathogenesis of frozen shoulder, a disease with typical symptoms of limited joint mobility, is not known, but it is certain that significant fibrosis occurs within the joint in patients with frozen shoulder. evels of systemic inflammation are now being studied in patients with shoulder cystic fibrosis in periarthritis. Both primary and secondary periarthritis of shoulder show a strong correlation with the overall inflammation level of patients. A related study on secondary frozen shoulder after rotator cuff repair indicated that half of the patients with secondary frozen shoulder had high systemic inflammation level [16]. Studies on patients with idiopathic frozen shoulder showed overexpression of inflammatory factors in subacromial bursae, mainly including IL-1α,

IL-1β, TNF-α, COX-1, and COX-2[17]. Studies have also suggested that RAGedependent levels of NF-kB associated inflammation are overexpressed in the articular sac in patients with idiopathic shoulder capsulitis [18]. As one of the important risk factors for frozen shoulder, diabetes, which leads to metabolic disorders and inflammation, needs to be taken into consideration. Currently, the outcome of fibrosis caused by diabetes has been extensively studied in the liver and cardiovascular system [19-20]. For the skeletal muscle system, diabetes may lead to fibrosis by increasing the production of fat precursors [21]. But the exact mechanism by which it increases the risk of frozen shoulder is unclear. Studies have also suggested that low levels of inflammation persist in the blood of young diabetic patients [22]. In the cardiovascular system, the persistent inflammation complicated by diabetes can lead to atherosclerosis [23]. Diabetes-mediated inflammation is currently thought to be the result of an immune response to hyperglycemia, fat in adipose tissue, and the production of inflammatory mediators by macrophages [24]. Admittedly, hyperglycemia induces activation of PKC. When PKC is activated by intracellular hyperglycemia, it has a variety of effection on gene expression. VEGF, TGF-β, NF-κB and PAI-1 is up-regulation. Meanwhile, eNOS is down-regulated expression. These gene expression changes are closely related to fibrosis.[6] The current main treatment for patients with frozen shoulder is intra-articular injection of sodium hyaluronate, with the addition of hormones if necessary. While, hormones further increase blood sugar levels, which obviously has a detrimental effect on patients with combined diabetes. Surgical treatment, although effective, patients with diabetes have a high risk of infection and the problem of poor wound healing in diabetic patients. As a result, the incidence of frozen shoulder is higher and treatment modalities are limited in diabetic patients. ESWT is a treatment that can significantly improve the pain and joint limitation of periarthritis, but there are few studies on patients with periarthritis in combination with diabetes, so this paper may end up including fewer cases, but the results of its statistical analysis will suggest the clinical significance of the effectiveness and safety of extracorporeal shock wave treatment in patients with periarthritis in combination with diabetes.

References

1. Millar Neal L, Adam M, Filip S. Frozen shoulder. .Nat Rev Dis Primers. 2022; 8: 59.
2. Daniel DLS, Santiago NL, Fany A. A Comprehensive View of Frozen Shoulder: A Mystery Syndrome. Front Med (Lausanne).2021; 8: 663703.
3. Gunnar JN, Ivar BJ, Cathrine B. Very High Prevalence of Frozen Shoulder in Patients With Type 1 Diabetes of ≥45 Years' Duration: The Dialong Shoulder Study. Arch Phys Med Rehabil. 2017; 98: 1551-1559.
4. Hasan ARA. Analytical Observational Study of Frozen Shoulder among Patients with Diabetes Mellitus. Joints. 2018; 6: 141-144.
5. Griggs Ryan B, Laird Don E, Donahue Renee R. Methylglyoxal Requires AC1 and TRPA1 to Produce Pain and Spinal Neuron Activation. Front Neurosci. 2017; 11: 679.
6. Michael B. The pathobiology of diabetic complications: a unifying mechanism. Diabetes. 2005; 54: 1615-25.
7. Lin Che-Li, Yang Ming-Ta, Lee Yu-Hao. Effect of the Critical Shoulder Angle on the Efficacy of Ultrasound-Guided Steroid Injection for Subacromial Bursitis. J Pers Med. 2022; 12: undefined.
8. Gcam MM, Mira M, Suzie N. Understanding the clinical profile of patients with frozen shoulder: a longitudinal multicentre observational study. BMJ Open. 2022; 12: e056563.
9. Chih-Hao C, Huan S, Poyu C. Arthroscopic Pan-Capsular and Transverse Humeral Ligament Release with Biceps Tenodesis for Patients with Refractory Frozen Shoulder. Medicina (Kaunas). 2022; 58: undefined.
10. Nihat A. Low-energy versus middle-energy extracorporeal shockwave therapy for the treatment of snapping scapula bursitis. Pak J Med Sci. 2017; 33: 335-340.
11. Xiangnan Y, Fenghua Z, Lixin Z. Analgesic Effect of Extracorporeal Shock Wave Treatment Combined with Fascial Manipulation Theory for Adhesive Capsulitis of the Shoulder: A Retrospective Study. Biomed Res Int. 2018; 2018: 3450940.
12. Dong-Zi C, Cun-Liang W, hong Q. Effectiveness of extracorporeal shock-wave therapy for frozen shoulder: A protocol for a systematic review of randomized controlled trial.Medicine (Baltimore). 2019; 98: e14506.

13. Saldiran Tülay Ç, Yazgan Pelin Y, Akgöl Ahmet C. Radial shock-wave therapy for frozen shoulder patients with type 2 diabetes mellitus: a pilot trial comparing two different energy levels.Eur J Phys Rehabil Med. 2022; 58: 412-422.
14. Oosterwijk AM, Nieuwenhuis MK, Van der Schans CP. Shoulder and elbow range of motion for the performance of activities of daily living: A systematic review. Physiother Theory Pract. 2018; 34: 505-528.
15. Hawker Gillian A, Samra M, Tetyana K. Measures of adult pain: Visual Analog Scale for Pain (VAS Pain), Numeric Rating Scale for Pain (NRS Pain), McGill Pain Questionnaire (MPQ), Short-Form McGill Pain Questionnaire (SF-MPQ), Chronic Pain Grade Scale (CPGS), Short Form-36 Bodily Pain Scale (SF-36 BPS), and Measure of Intermittent and Constant Osteoarthritis Pain (ICOAP). Arthritis Care Res (Hoboken). 2011; null: S240-52.
16. Yaying S, Jinrong L,Luo Zhiwen L. The Serum from Patients with Secondary Frozen Shoulder Following Rotator Cuff Repair Induces Shoulder Capsule Fibrosis and Promotes Macrophage Polarization and Fibroblast Activation. J Inflamm Res. 2021; 14: 1055-1068.
17. Yun-Mee L, Eunyoung H, Chul-Hyun C. Inflammatory cytokines are overexpressed in the subacromial bursa of frozen shoulder. J Shoulder Elbow Surg. 2013; 22: 666-72.
18. Toshihisa Y, Yoshihiro H, Akira A. RAGE-dependent NF-kB inflammation processes in the capsule of frozen shoulders. J Shoulder Elbow Surg, 2020; 29: 1884-1891.
19. Romina L, Eddison GL, Fernando B. Advanced Liver Fibrosis Is Common in Patients With Type 2 Diabetes Followed in the Outpatient Setting: The Need for Systematic Screening. Diabetes Care, 2021; 44: 399-406.
20. Mohanraj R, Partha M, Sándor B. Cannabinoid receptor 2 activation alleviates diabetes-induced cardiac dysfunction, inflammation, oxidative stress, and fibrosis. Geroscience. 2022; 44: 1727-1741.
21. Bénédicte C, Rémi M. Diabetes-induced skeletal muscle fibrosis: Fibro-adipogenic precursors at work. Cell Metab. 2021; 33: 2095-2096.
22. Aida S, Cathrine B, Martin H. Sustained low-grade inflammation in young participants with childhood onset type 1 diabetes: The Norwegian atherosclerosis and childhood diabetes (ACD) study. Atherosclerosis, 2023; undefined: undefined.
23. Anastasia P, Grechko Andrey V, Poggio P. The Diabetes Mellitus-Atherosclerosis Connection: The Role of Lipid and Glucose Metabolism and Chronic Inflammation. Int J Mol Sci. 2020; 21: undefined.
24. Afiat B, Nofri R, Imam TA. Type 2 Diabetes and its Impact on the Immune System. Curr Diabetes Rev. 2020; 16: 442-449.