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Shock Wave Treatment and Rotator Cuff Tears: Rightly Blamed or Victim of Methodological Bias?

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Abstract

Focused shock waves are a frequently used non-invasive therapeutic option for the treatment of rotator cuff calcifications. Over the last 30 years, numerous studies have been published that support its high level of recommendation. Reports of complications are isolated and very infrequent. In this communication, we analyze why there are no valid arguments to relate the application of shock waves with rotator cuff injuries.

Keywords: Shock wave, Rotator Cuff, Complications

Introduction

The following is a letter sent to the Editor of the Korean Clinics in Orthopedic Surgery Journal on an article that we consider having serious methodological flaws that was published in said journal. Unfortunately, we were denied the opportunity that any reader of a scientific publication should have, and at the same time, the authors were denied the opportunity to defend their position. They are invited to publish a response in our Journal, which will be respected.

Dear Editor,

Focused extracorporeal shock wave therapy (ESWT) has a high degree of recommendation to treat rotator cuff calcifications [1]. It is considered "the most thoroughly investigated minimally invasive treatment option" for this condition [2]. It has proven to be a safe and effective procedure in the short to midterm [3].

Some of the signatories of this letter have between 20 and 30 years of experience with the method, and some of us are also specialists in shoulder surgery. We have always been aware and search for the possibility of complications related to shock waves. For this reason, we carefully read the study "Posterior Rotator Cuff Tears (RCTs): Is Extracorporeal Shockwave Therapy a Risk Factor?" by Han et al. [4]. There are a series of considerations that we would like to make:

The alleged arguments used by the authors trying to support that ESWT generates tissue injuries are not valid and are based on their free interpretation of the literature

The authors cite two studies by Wang et al. [5,6] in which according to them "Wang et al. reported that neovascularization ingrowth may be stimulated by repeated microtrauma associated with ESWT." However, the word "microtrauma" is not mentioned in either publication. In the study that analyzes the effects of ESWT on osteoarthritis [5], Wang's main findings are that ESWT is chondroprotective. The mechanism of action is succinctly described but at no point is "trauma" or "microtrauma" mentioned as a

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mechanism of action.

The second study cited [6] was published 20 years ago. Much has been learned since then about the mechanism of action of shock waves. In the study, it is concluded that shock wave treatment significantly improved the healing of a tendon graft to bone in a bone tunnel in anterior cruciate reconstruction in rabbits. Nowhere in the study is it mentioned that "trauma" or "microtrauma" is part of the mechanism of action.

The authors also cite a systematic review by Mouzopoulos et al. [7] to support that ESWT can cause tendon injuries. However, Mouzopoulos's study bases his claim on a study by Delvecchio [8]. That study does not refer to tendons, instead describing the findings of renal injuries during lithotripsy. The authors acknowledge that the clinical significance of their findings in kidneys is unclear [8].

Han et al. furthermore use a case report of an Achilles tendon injury to make the claim that ESWT "might" cause rotator cuff tendon injury. They state that "Lin et al. demonstrated that Achilles tendon injury might be related to ESWT." The word "might" is used in English when there is no certainty regarding a fact, so linking it to the word "demonstrated" does not make semantic sense. Beyond this, Lin et al. [9] also jump to conclusions. They report the case of spontaneous rupture of the Achilles tendon with a history of having received shock wave treatment to which they attribute the injury. Lin et al. state that risk factors for Achilles tendon rupture include prior surgery, steroid injection in the Achilles tendon, and possibly long-term NSAID use [9]. The patient described had all of these risk factors, yet it was decided to attribute the injury to the shock waves solely because the patient had received a low-energy session 2 months earlier.

Achilles tendon is the most injured tendon in the human body [10] and in most cases; patients have not received ESWT previously.

Tarantino et al. [11] describe in detail the long list of causes that can contribute to the acute rupture of the Achilles tendon. We do not have detailed clinical information about the case described by Lin et al. but evidently, it has been simpler to attribute the rupture to a session of shock waves in a very biased approach to the issue.

Finally, the authors cite a study published by Rompe 26 years ago [12] that warns that high levels of shock wave energy (above those usually used to treat rotator cuff calcifications) can cause histological changes in the tendon of Achilles of rabbits. In any case, animal experiences with shock waves should not be extrapolated directly to human beings since, as Chen et al. have stated, the tolerance to ESWT was different for different species [13].

The clearest response to the authors' erroneous interpretation of the mechanism of action of ESWT can be found in a publication by d'Agostino et al. [14]. When describing the mechanism of action, d'Agostino's publication states that when applied in non-urological indications, the mechanisms of action are not related to a direct mechanical effect such as in lithotripsy, but to pathways of biological reactions, that are triggered by acoustic stimulations, through "mechanotransduction" [14]. Hence, the "mechanical model" of urological lithotripsy has been substituted by a "biological model" [14] when treating tendons.

The peculiar interpretation of the information published by other authors goes beyond shock wave studies in the paper by Han et al. The authors state that "corticosteroid injections have been recommended as first-line clinical treatments," citing as reference a study by Cardoso et al. [15]. However, Cardoso's study says exactly the opposite. The study highlights that corticosteroids are detrimental to tendons and are significant negative effects on tendon cells [15].

It is also surprising that at no point is rehabilitation mentioned as one of the first-line therapies for both calcified and non-calcified tendinopathies.

There is evidence of the safety of shock waves with respect to the rotator cuff and other tissues

In addition to the enormous number of clinical studies that demonstrate the safety of shock waves [1], there is another type of research that supports it. Cyteval et al. [16] performed a Magnetic Resonance Imaging (MRI) study 2 h before and 15 days after the application of focused shock waves on rotator cuff calcifications; in addition, in 5 of the included patients, an additional MRI study was carried out 6 h after ESWT. The authors concluded that shock wave therapy has no early complications or significant impact on the anatomic structures of the shoulder.

Brañes et al. [17] performed histological and immunohistochemical analysis in patients operated on for rotator cuff rupture, comparing a group that had previously received shock waves and another group that had not. ESWT induced neovasculogenesis, angiogenesis, and lymphangiogenesis as well in tendons with mild and moderate grade of degeneration. The authors do not report the presence of injuries.

Lorbach et al. analyzed the influence of a failed pre-operative ESWT on the clinical outcome after arthroscopic removal of the calcific deposit [18]. Twenty-four patients in their series (53%) underwent pre-operative ESWT. There were no significant differences in terms of clinical outcome between patients who received ESWT and those who did not [18]. The authors conclude that ESWT can be included in the treatment algorithm before arthroscopy without reducing the success rates of it [18].

Rebuzzi et al. [19] compared the results of shock wave treatment versus arthroscopic surgery in a group of 50 patients with chronic calcific tendonitis. They found no significant differences in outcomes at a 2-year follow-up.

Daecke et al. [20] performed a 4-year clinical follow-up after the application of shock waves in rotator cuff calcifications without finding complications.

The safety of ESWT has also been studied in other branches of medicine such as urology [21, 22], neurology [23], and cardiology [24-26]. The use of shock waves in cases of refractory angina pectoris and post-acute myocardial infarction is developing as a new therapeutic option [24,25]. Liu et al. [26] applied focused shock waves in the left ventricle of rats to evaluate the safety of the procedure in the treatment of cardiac conditions. ESWT had no significant influence on rat hemodynamics indices, did not affect left ventricular function, and myocardial inflammatory response and fibrosis changes were not detected with transmission electron microscopy.

The methodology used in the study is highly questionable

The primary issue with the study by Han et al. is its retrospective design, which inherently limits the ability to establish causation. The authors suggest that ESWT is a risk factor for posterior RCTs based on an association found in their retrospective analysis. However, as is well-known in epidemiological research, association does not imply

causation. Retrospective studies are prone to various biases, including recall bias and selection bias, which can significantly affect the validity of the findings. Moreover, the retrospective nature of the study means that the temporal relationship between ESWT and the development of posterior RCTs cannot be firmly established. It is unclear whether the ESWT preceded the RCTs or if patients with early, undiagnosed tears were more likely to receive ESWT, leading to a reverse causation scenario.

An additional concern is the potential for indication bias. The study found that calcific deposits were more frequently observed in Group P (patients with posterior RCTs) compared to Group A (patients with anterior RCTs). ESWT is more frequently indicated for the treatment of calcific tendinitis, which may explain why patients in Group P were more likely to receive ESWT. This suggests that the higher prevalence of ESWT in Group P could be a result of the underlying condition (calcific deposits) rather than a direct risk factor for posterior RCTs. Thus, patients with calcific tendinitis were already more prone to receive ESWT, potentially confounding the results. However, it should be noted that calcific deposits may not fully meet the criteria for a confounder since they are likely an indication for ESWT and thus part of the causal pathway rather than an independent variable.

The study states that logistic regression analysis was performed "to determine the independent variable for two different located RCTs." However, this statement is imprecise. It is unclear what the authors mean by "independent variable for two different located RCTs." Furthermore, the study does not present which variables were controlled for in the logistic multivariable model.

The results are presented in an awkward manner. For instance, the paper states, "A high risk of anterior RCTs was found in FI of the SST (odds ratio [OR], 12.81; 95% confidence interval [CI], 3.77–43.46, P < 0.001). ESWT history was likely to have posterior RCTs (OR, 0.04; 95% CI, 0.01–0.21, P < 0.001)." This presentation is awkward and likely incorrect. A clearer and more accurate way to present these findings would be to state that the presence of FI of the SST was more likely associated with anterior than posterior tears, whereas ESWT was more likely associated with posterior than anterior tears.

To make a robust conclusion about the potential risks of ESWT, a prospective cohort study or a randomized controlled trial would be more appropriate. Such study designs would allow for better control of confounding variables and a clearer establishment of temporal relationships, thereby providing more reliable evidence regarding the causative role of ESWT in posterior RCTs.

The authors acknowledge some limitations, including a small sample size and the lack of detailed information on ESWT parameters such as type, impulses, interval, and intensity used.

The study included only 24 patients in the posterior rotator cuff tear (RCT) group. This sample size is inadequate for drawing robust conclusions, especially given the potential variability in patient responses to ESWT. A larger sample size is necessary to ensure sufficient statistical power and to minimize the risk of Type II errors. Without an adequate sample size, the study is prone to false negatives, potentially overlooking significant differences between groups.

In addition, the study does not provide a detailed analysis of the different types and intensities of ESWT. Various studies have shown that the therapeutic effects of ESWT can vary significantly based on these parameters. For example, high-energy versus low-energy ESWT can have different impacts on tissue healing and pain reduction [27]. Without this analysis, it is difficult to ascertain whether the observed effects are due to ESWT in general or specific to certain treatment protocols. Furthermore, the study should have stratified patients based on these variables to provide a clearer understanding of how different ESWT protocols affect rotator cuff integrity.

In addition, the reliance on patient-reported data for steroid injection and ESWT history introduces further potential for recall bias and inaccuracies.

Of the 24 patients in Group P, 19 patients reported a history corticosteroid injection. As previously discussed, corticosteroid has been shown to be tenotoxic and introduces another confounder with potential for bias in this study. An additional important clinical factor that is omitted by the authors is a history of ultrasound-guided needling. The authors of this study report that they "had to ignore the ultrasound-guided needling history in patients" as they were reliant on patient-reported history of procedures and found this data to be "vague". The authors previously claim these rotator cuff injuries to be due "microtrauma," which is not part of the mechanism of action of ESWT but certainly is a key component of needling procedures.

Conclusion

While the study by Han et al. raises an interesting hypothesis, the limitations of the retrospective design, the potential for confounding, the indication bias, and the unclear presentation of logistic regression results mean that the conclusion – that ESWT is a risk factor for posterior RCTs – cannot be confidently supported.

The basic objective of science is the search for truth. It is unlikely that this will be achieved by not making a correct interpretation of literature information and facts.

Declaration of patient consent: The authors certify that they have obtained all appropriate patient consent forms. In the form, the patient has given his consent for his images and other clinical information to be reported in the Journal. The patient understands that his name and initials will not be published, and due efforts will be made to conceal his identity, but anonymity cannot be guaranteed.

Conflicts of Interest: Nil. **Source of Support:** None.

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