ORIGINAL ARTICLE

CONTENTS

Radial shock wave therapy with "Intelect PRW Lite" for calcifying tendinopathy of the shoulder, comparative effectiveness with conventional physical therapy and follow up data

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ABSTRACT

Aim: To reveal the criteria for effective treatment of this pathology and to compare it with the conventional physical factors.

Materials and Methods: The research has been taken on 60 people, A control group (CG), including 30 people, treated with basic therapy and experimental group (EG). including 30 people, treated with the same basic therapy and RSWT once per week for seven consecutive weeks. The effect of the treatment was shown by: sonographic examination before and after treatment, physical tests for motor skills in shoulder region, scale of pain and the range of motion (ROM).

Results: The results have high statistical significance ($p<0,001$) for both groups. The comparision between EG and CG ($p<0,001$) proves that usage of RSWT reduces the pain quicker and restores mobility in the shoulder region in a shorter period than conventional physical therapy and only in the EG there is reduction in the parameters of the calcifications and total disappearance in the follow up.

Conclusions: The results have high statistical significance ($p<0,001$) for both groups. The statistical difference between EG and CG ($p<0,001$) proves that usage of RSWT reduces the pain quicker and restores mobility in the shoulder region in a shorter period than conventional physical therapy and only the patients in the EG have reduction in the parameters of the calcifications and total disappearance in the follow up.

KEY WORDS: physical therapy, shoulder, tendinopathy, shockwave

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INTRODUCTION

Radial shock wave therapy (RSWT) is a well-known modality for treatment of different musculoskeletal conditions [1]. However, in the treatment context of chronic calcifying tendinopathy of the shoulder, its effectiveness is still controversial [2-5]. The lack of control groups and follow-up data are the main weakness of most of these studies.

Calcifying tendinopathy, also known as calcific tendonitis, is a condition characterized by the formation of calcium crystal deposits in one or several tendons, most often in the shoulder. The exact cause of calcific tendinopathy remains unknown. Here are some key points about its etiology [6,7].

- It is not typically caused by trauma or overuse, and it is rarely part of a systemic disease
- It may be associated with certain conditions such as diabetes, thyroid disorders, or kidney stones
- Some reports suggest a genetic predisposition for the development of intratendinous calcific deposits
- Tissue tears and natural tissue breakdown (degenerative changes) increase the chance of these deposits occurring
- The calcium deposits result from the deposition of calcium hydroxyapatite within the substance of a tendon. This is thought to be due to decreased oxygen tension, leading to fibrocartilaginous metaplasia and secondary mineralization

The inflammation around the deposits and increased intratendinous pressure are thought to contribute to the pain associated with this condition. However, the exact mechanisms are still not fully understood and research is ongoing.

AIM

The purpose of this clinical study is to evaluate the additive value of radial shock wave therapy as adjunctive

modality in treatment of chronic calcifying tendinopathy of the shoulder in comparison with the conventional modalities alone and to present follow up data for the long-term efficacy of this treatment combination.

MATERIALS AND METHODS

The clinical study involved 60 patients diagnosed with calcifying tendinopathy due to different etiological factors (chronic micro traumatic damage to the tendons, acute trauma and metabolic syndrome) [2]. Informed consent was received by each patient included in the study. Only adult patients were enrolled (18-58 years, 13 men and 17 women). The Ethics Committee of the MBAL St. Sofia Hospital (Sofia, Bulgaria) has reviewed and approved this study.

For the aim of the study the patients were divided into 2 groups and we used the model of autocontrol.

1. Control group (CG) consisting of 30 patients who were treated with basic physiotherapy (TENS, kinesiotherapy and BIC) during a course of 7days.
2. Experimental group (EG) of the same 30 patients who were treated with basic physiotherapy (TENS, kinesiotherapy and BIC) in combination with RSWT during a course of 7 weeks (once per week) after the first week of basic physiotherapy.

The efficacy of the treatment was evaluated by: sonographic examination [7,8] before and after treatment (after 1 month and after 3 months), physical tests for motor skills of the shoulder region (SPADI), scale of pain (VAS) and the range of motion (ROM).

The two groups were treated in two different medical centers in order to eliminate the subjective factors. The basic physiotherapy was funded by the National Health Insurance Fund, whereas the shockwave therapy was covered by the patients.

Objective criteria for including and comparing the two groups:

1. History and duration of the illness
2. Number of affected ligaments and size of the calcifications according to the sonographic examination
3. Range of motion – ROM
4. Pain scale – VAS (visual analogue scale)
5. SPADI (Shoulder Pain and Disability Index)

THERAPEUTIC PROCEDURES

RSWT was done once per week for 7 weeks. Prior to the procedure, a sonographic examination was performed in order to measure and mark the calcifications. The dosage for each individual patient was based on the following:

- The total hit counts depend on the number of affected muscles but does not exceed 6000 per day.
- The subjective level of discomfort for the patient – the aim was to reach the maximum tolerance threshold while not causing pain.

The patients were instructed not to take any nonsteroid anti-inflammatory drugs (NSAIDS) for the next 4 hours after the therapy as well not to carry out any other physical therapy in the same day.

INCLUSION CRITERIA

1. Age over 18 and under 70 years
2. Informed consent
3. History of pain no more than a year

EXCLUSION CRITERIA

1. Pregnancy
2. Ade under 18 and over 70 years
3. Cancer
4. Not signed informed content

SONOGRAPHIC DATA

In order to measure the density of the calcifying tendinopathy, we used a 3-grade scale proposed by the Cohen M. et al [9]. It describes the possible findings as follows:

Type 1 – full thickness shadow

Type 2 – echogenic with non-full thickness shadow

Type 3 – without shadow on the underlying bone

The obtained data together with the medical history were collected in a personal patient's file.

RADIOLOGIC DATA

We have used the Radiological classification of Calcifying Tendinitis by Gartner and Heyer, which describes the possible findings as follows:

Type 1 – clearly circumscribed and dense, formative

Type 2 – clearly circumscribed, translucent, cloudy and dense

Type 3 – cloudy and translucent, resorptive.

RSWT TREATMENT PROTOCOL

During the procedure the patient is positioned comfortably, and the posture is modified for every treated tendon. The calcifications are measured sonographically and then marked. The transmitter is situated over the marked places and is moved circularly for 2000 hits on certain area. Communication with the patient is carried out during the procedure in order not to reach the pain threshold. Each target zone received 2000 hits but no more than 6000 in one day.

STATISTICS

The collected data was statistically analyzed by means of descriptive statistics, t-test, chi-square and one-way

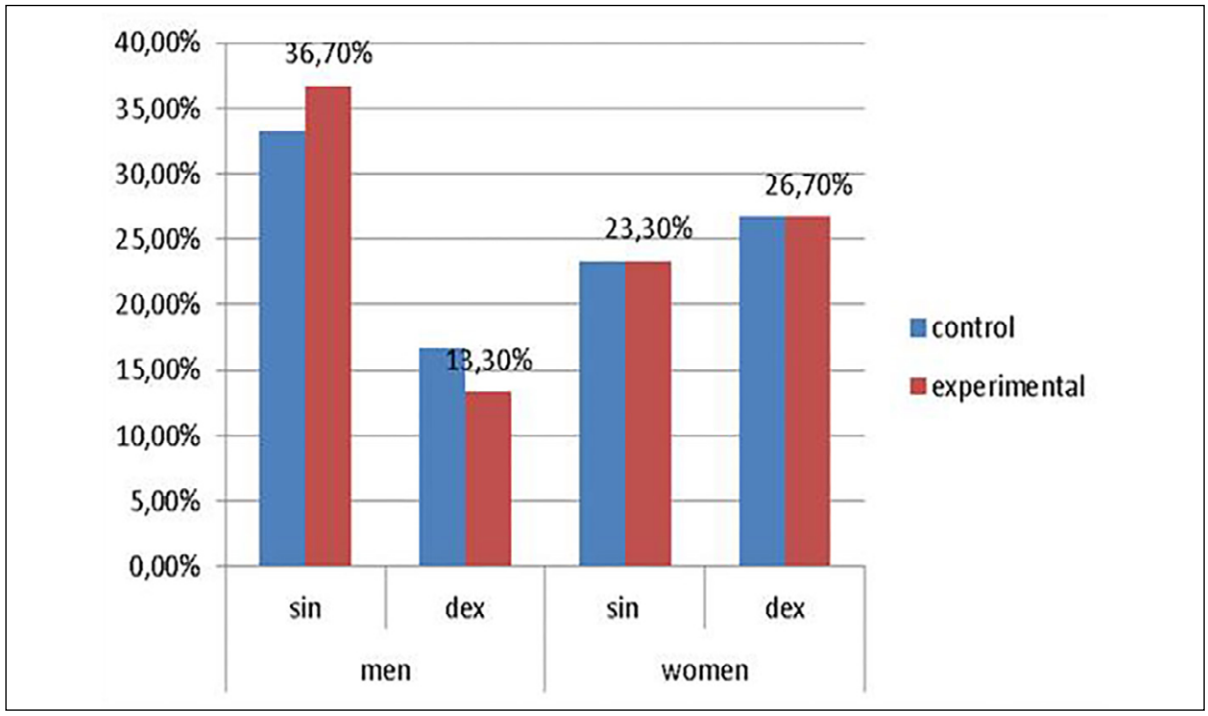

Fig. 1. Sex distribution (1) and distribution of the affected shoulder – left (sin) or right (dex), (p=0,067).

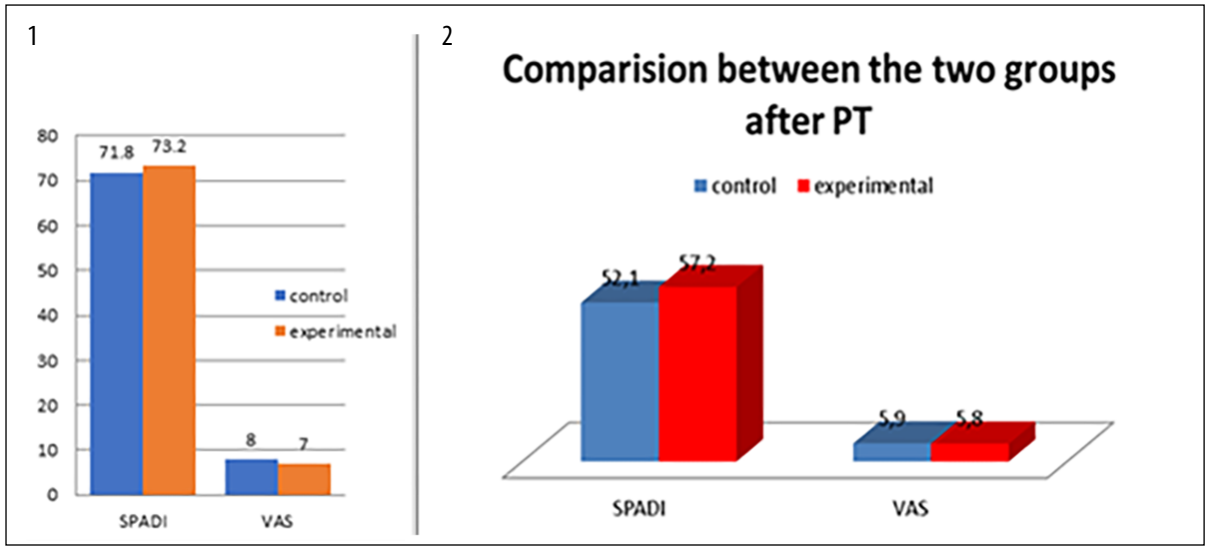

Fig. 2. Comparison of SPADI and VAS before start of PT (1) and after PT (2).

ANOVA. Statistical significance was set at p <0.05. All statistical analyses were performed using SPSS v. 20.

RESULTS

The initial data are favorable for further comparison of the provided treatment modalities.

The statistical analyses revealed that there are no statistically significant differences between the two groups in terms of their sex distribution (Fig.1), p=0,069. The left shoulder joint in men is statistically more affected than in women (Fig. 2) (p=0.011). The mean age of the patients and the history of pain duration are without statistical difference for both groups.

The comparison of SPADI and VAS scores before starting of PT (Fig. 2(1)) and after PT (Fig.2(2)) for both groups revealed equivalent decrease in the measured parameters without statistical significance for the outcome, p=0.004.

Similar treatment outcomes in both groups after PT revealed positive effects of the basic physiotherapy which confirmed the homogeneous distribution of the patients in the study groups. The additional application of RSWT however led to different results.

The statistical analyses of the size of calcifications in the experimental group (EG) before starting of PT (Fig.3(1)) and the size of calcification in EG after RSWT (Fig.3(2)) revealed statistically significant difference by T-TEST of pairs(p < 0.05).

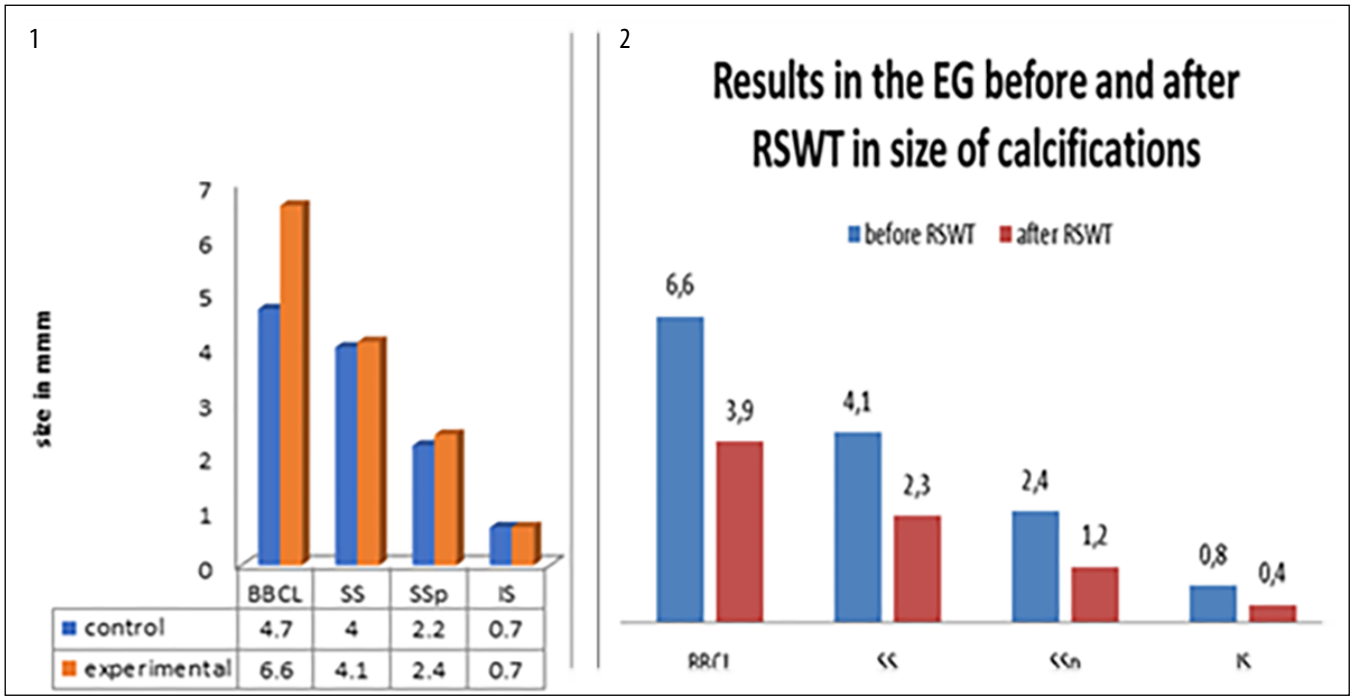

Fig. 3. Comparison of the size of calcifications before starting of PT (1) and the size of calcification in EG after RSWT (2), p=0.001.

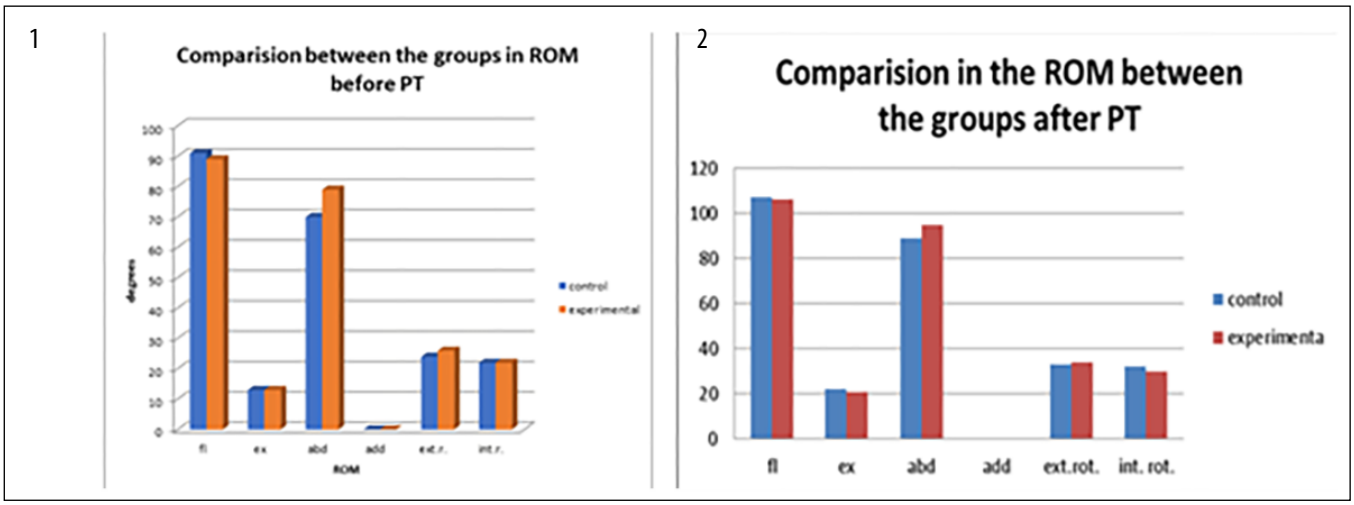

Fig. 4. Comparison of the ROM before start of PT (1) and after PT (2) in both CG and EG., (p>0.05).

A similar tendency was observed when comparing the ROM before start of PT (Fig.4(1)) and after PT (Fig.4(2)) for both CG and EG. It confirms again the homogeneity of the patients and the positive effect of basic physiotherapy.

The additional application of RSWT resulted in statistical differences in SPADI and VAS scores in the EG by Levene's Test, (p<0.05) (Fig. 5).

Short-axis view of the SSP tendon with intratendinous bursal side migration pattern of a softly hydrated fragment (white void arrow) of calcific deposits with sub-bursal space involvement (C,). Del: deltoid, Cor: coracoid, HH: humeral head, blue lines: subacromial bursa, white dotted lines: cartilage, white lines: outer surface of the rotator cuff tendons.

DISCUSSION

The exact causes and mechanisms of the chronic calcifying tendinopathy of the shoulder are still not fully understood [6]. Despite the etiological factor and the variety of clinical symptoms, the main attribute of this pathological condition is the presence of calcified tissue [8]. In patients with chronic micro traumatic damage, the calcifications are usually smaller but are presented in all the tendons of the rotator cuff [10]. In patients with

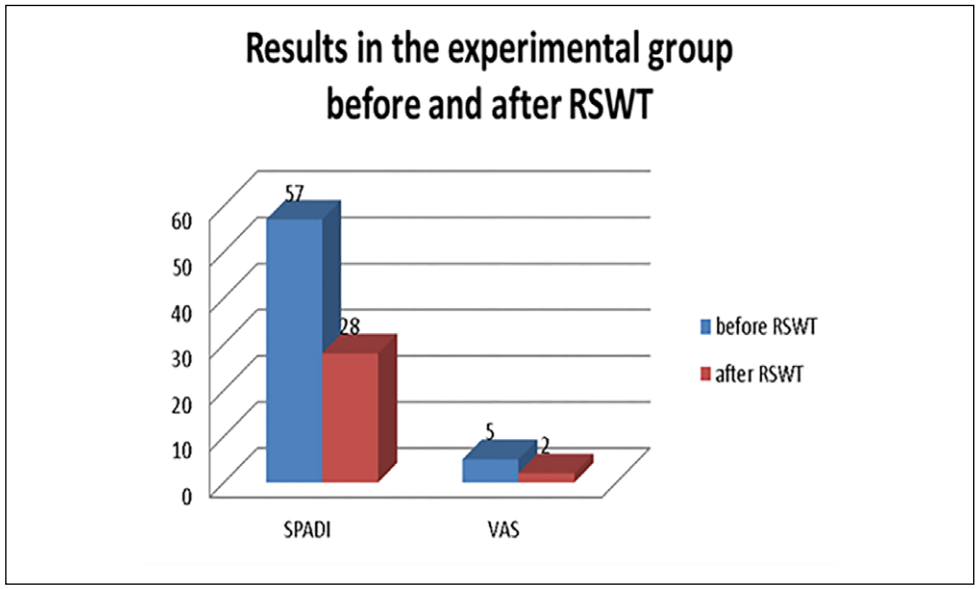

Fig. 5. Comparison of SPADI and VAS values before start of RSWT and after RSWT, p<0,05

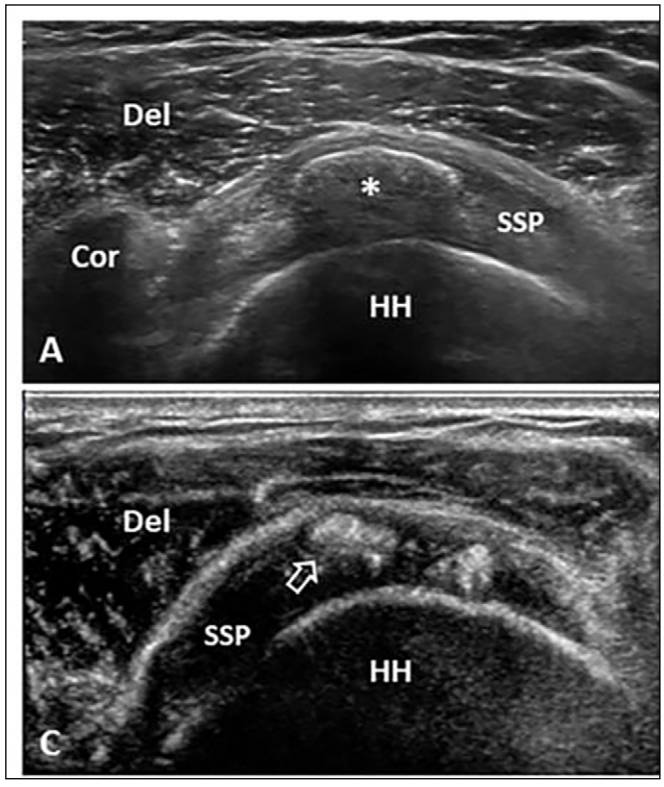

Fig. 6. Demonstration of the change in the calcification before (A) and a month after therapy (C). Short-axis view of the supraspinatus (SSP) tendon with elliptical calcification (asterisk) in resting phase – i.e., type 1 Gartner and Heyer (A).

acute traumatic injuries, the calcifications are larger, and thus needed more therapy sessions to fully resorb. In patients with metabolic syndrome, the calcifications are multiple and could be found in almost all the tendons of the rotator cuff. They are managed quickly but the recurrence is also often depending on the control of systemic condition [11,12].

The presence of calcified tissue requires careful selection of physiotherapeutic modalities to prepare the local site for faster disintegration and further resorption of the calcificates. We could not find other articles comparing the effect of the two modalities – PT and RSWT that have similar to our materials and methods.

The mechanism of action of TENS and IFC involves both peripheral and central mechanisms.

- Peripheral Mechanisms: TENS and IFC stimulate the nerves in the area where the pain is felt. This stimulation helps to block the transmission of pain signals along the nerves to the brain, a theory known as the Gate Control Theory. Additionally, these modalities can stimulate the body to produce its own pain-relieving substances, called endorphins [13].
- Central Mechanisms: TENS and IFC may also exert their effects centrally in the brain, where they may influence the perception of pain [13].

CONCLUSIONS

Combining RSWT with other physical factors and kinesiotherapy statistically shortened the length of the therapeutic process. Follow-up appointments on the first month showed further reduction in the size of the calcifications, and that tendency was present in the third month as well.

The results of our study revealed that the combination of basic physiotherapy (TENS, kinesiotherapy and BIC) and RSWT plays in coherence amplifying their effects. The results in their integrity revealed that there is a significant improvement in the SPADI and VAS scores, ROM and reduction in the size of calcifications after additional application of RSWT in the treatment plan of the experimental group (p<0.001). None of the patients reported side effects or discontinued the treatment.

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CONFLICT OF INTEREST

The Authors declare no conflict of interest

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