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Pain Management Optimisation by an Ultrasound-Guided Analgesic Technique in Outpatients with Plantar Fasciitis during High-Energy Extracorporeal Shock Wave Therapy

Angelo Chierichini[1,2], Giorgia Spinazzola[1,2], Carla Conti[3], Michela Saracco[3], Alessandro Vergari[1,2], Nicola Continolo[1,2], Giuliano Ferrone[1,2], Marco Rossi[1,2]

[1]Department of Emergency, Intensive Care Medicine and Anesthesia, Fondazione Policlinico Universitario A. Gemelli IRCCS, Rome, Italy
[2]Istituto di Anestesiologia e Rianimazione, Università Cattolica Del Sacro Cuore, Rome, Italy
[3]Department of Orthopedic Surgery, Fondazione Policlinico Universitario A. Gemelli IRCCS, Rome, Italy

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Abstract

Objective: Several studies have demonstrated the efficacy of high-energy extracorporeal shock wave therapy (HESWT) for the treatment of painful foot diseases. A crucial complication of HESWT is the appearance of pain with the subsequent interruption of the procedure. The aim of this study was the evaluation of ultrasound (US)-guided posterior tibial nerve block (PTNB) efficacy in outpatients who discontinued the first application of HESWT due to surge of moderate-severe pain.

Methods: Twenty-one patients, scheduled for HESWT due to plantar fasciitis, who interrupted the treatment for surge of pain (numeric rating scale [NRS] ≥ 5), were enrolled. After interruption of the first treatment, the patients received US-guided PTNB for every subsequent HESWT session. The same skilled anaesthesiologist performed an US-guided PTNB all the times. Once the nerve was identified, the needle was inserted and 5 ml mepivacaine 1% were injected. Intensity of pain during each procedure by NRS and evaluation of patient's adherence to the treatment were detected.

Results: The HESWT was split into only three applications giving in average about 0.25 mJ mm^{-2}, and all patients completed the treatment sessions. US-guided PTNB showed a significant reduction of NRS ($P < 0.01$) between the first HEWST without anaesthesia and the three subsequent treatments under peripheral block.

Conclusion: US-guided PTNB resulted a valid support for the HEWST in outpatients with plantar fasciitis because it reduced the pain during the procedure, allowing to minimise the patient discomfort and to give the therapeutic doses just in three sessions.

Keywords: Loco-regional analgesiapainfoot diseasesshock wavenerve block

Introduction

Plantar fasciitis and Achilles tendinopathy are the most common causes of heel pain.[1,2] Usually, the painful foot diseases are self-limiting conditions and treated nonoperatively in the majority of patients.[3–5] Traditional nonoperative treatment of chronic foot diseases consists of rest, anti-inflammatory medications, and physical therapy modalities. In the majority of cases, nonoperative measures are effective; however, 10-20% develop chronic pain and may require surgery.[1]

High-energy extracorporeal shock wave therapy (HESWT) has been proposed as a potential method of treating patients affected by these chronic diseases without the need to stop weightbearing.[6]

Corresponding Author: Giorgia Spinazzola; E-mail: Giorgia.spinazzola@policlinicogemelli.it

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Shock waves have both a direct and indirect effect on treated tissues, the former being the result of the energy of the shock wave transferred to the targeted tissues, while the indirect effect is the result of the production of cavitation bubbles in the treated tissue.[7,8] Both the direct and indirect effects produce a biological response in the treated tissues.

To date, multiple publications[9–15] have focused on the evaluation of a clinically relevant effect of shock wave application on painful foot disease. These studies evaluated the efficacy of both high-energy shock wave, applied in a single session with local or regional anaesthesia, and low-energy shock wave applied repetitively without local anaesthesia or with topic anaesthetic cream.

Often a crucial complication of HESWT is the appearance of pain with the subsequent interruption of the procedure.[2,12] The consequences are a reduced patient compliance, need of a deep sedation, and more sessions for the treatment.

The aim of this study was to evaluate the efficacy of ultrasound (US)-guided posterior tibial nerve block (PTNB) in outpatients who discontinued the first application of HESWT for the treatment of plantar fasciitis due to the surge of moderate-severe pain.

Methods

Patient Selection

This study was conducted in Orthopaedics' Ambulatory Ward of Fondazione Policlinico Universitario A. Gemelli IRCCS in the centre of Italy. We included all outpatients scheduled for HESWT for the treatment of plantar fasciitis between 1 May 2019 and 31 August 2019. Ethics institutional review committee of Fondazione Policlinico Universitario A. Gemelli IRCCS approved this study (approval number 23234/19). Patients included in the study expressed the consent to participate before the inclusion. The study was registered on clinical trial.gov (registration number: NCT 03918434, registration date: June 4, 2019).

Main Points

- High-energy extracorporeal shock wave therapy (HESWT) is the most widely treatment for the plantar fasciitis. Unfortunately, this therapy is burdened by the occurrence of significant pain such as to require the treatment interruption and the need for sedation or periprocedural analgesia, which prevent early Hospital discharge in outpatients.
- In outpatients affected by plantar fasciitis, the execution of the ultrasound (US)-guided posterior tibial nerve block allows to complete the HESWT without affecting its effectiveness.
- The application of US-guided posterior tibial nerve block is an effective analgesic technique in outpatients with painful foot disease, allowing a quick Hospital discharge without pain or walking difficulties.
- The US-guided posterior tibial nerve block during HESWT may be useful in shortening the plan of treatment with a positive cost-effectiveness balance.

The patients were enrolled if they presented all of the following criteria:

- History of plantar fasciitis at least 6 months long
- Unsatisfactory subjective result (numeric rating scale [NRS] score persistently ≥4 for pain during the first few steps of walking in the morning] after at least 6 months of conventional therapy (≥4 weeks of physical therapy, and ≥4 weeks course of non-steroidal anti-inflammatory medications)
- HEWST indication
- Application of HEWST at 1500 shots of focused shock waves with an energy of 0.15 mJ mm^{-2}
- First treatment discontinued for surge of pain (NRS ≥ 5).
- American Society of Anesthesiology (ASA) physical status I and II

The exclusion criteria were

- Patient < 18 years
- Pregnancy
- Peripheral circulatory disorders
- Arthrosis of the foot or ankle, as confirmed by X-ray diagnosis
- Skin lesions on the foot
- Allergy to local anaesthetic
- Neurologic abnormality (impaired deep tendon reflexes, motor or sensory deficit)

Study Protocol

The HESWT was applied by a mobile therapy unit designed for orthopaedic use (Ossatron, HMT: High Medical Technologies, Switzerland), with the shock wave head suspended by an articulating arm with a flexible movement of the head in three planes. Ossatron is an electrohydraulic 'spark-gap' system that generates focused shockwaves, high energy, and very short duration pressure waves, with a large focal area (4 × 42 mm^2/7 × 73 mm^2). Energy levels are adjustable to 14 different steps. The depth of the treatment can be adjusted from 0 to 100 mm from the body surface. Routinely, HESWT with 1500 shots of focused shock waves is given once every 2 weeks using an energy of 0.15 mJ mm^{-2} and a frequency of 2.3 Hz for a maximum of six therapy sessions.

After interruption of the first treatment of HESWT for moderate-severe pain evaluated by NRS, the patients were subsequently rescheduled for the shock wave therapy under US-guided PTNB. This analgesic procedure was repeated for every subsequent session of HESWT.

With the patient lying supine and the foot externally rotated, a skilled anaesthesiologist performed the US-guided PTNB,

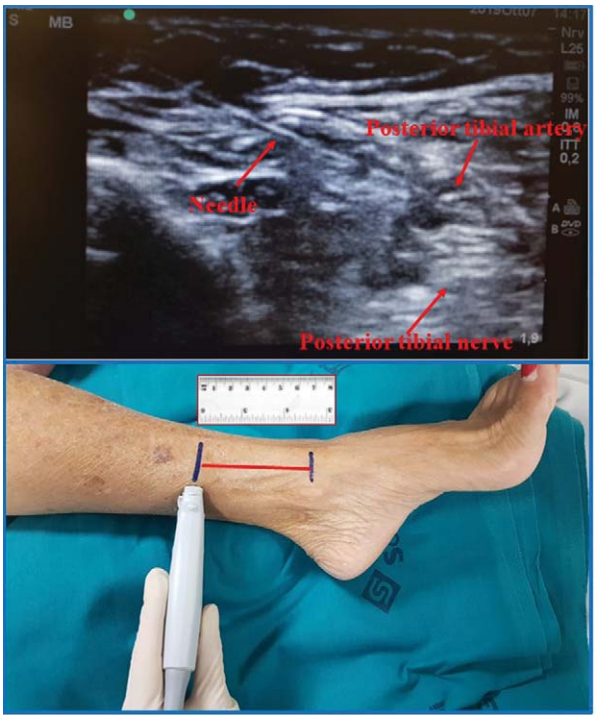

Figure 1. Ultrasound-guided posterior tibial nerve block in-plain.Note: The image below illustrates the execution site of the posterior tibial nerve block. The image above shows the ultrasound-guided execution in plain of the posterior tibial nerve block.

finding the posterior tibial nerve between the middle and the distal third of the leg, about 6-8 cm proximally to the tibial malleolus (Figure 1). Once the nerve was identified, the needle (35 mm long, 24 gauge, UPC Polymedic) was inserted in-plain and after careful aspiration mepivacaine 1% (5 mL) was injected.

Before the beginning of HESWT, the cutaneous sensory blockade by US-guided PTNB was evaluated using pinprick tests in the tibial nerve cutaneous territories (heel and sole of the foot).

After each treatment, the patient was immediately discharged from the Orthopaedics' ambulatory ward after evaluation of walking ability.

Measurements

During the protocol, the intensity of pain was detected, after 5 minutes from the start of each treatment, by NRS (between 0 and 10 points, where Zero usually represents 'no pain at all' whereas 10 represents 'the worst pain ever possible').[16] The sensitive block duration was evaluated by pinprick test (defined as a test for cutaneous pain receptors).[17]

The efficacy of HESWT was evaluated using the American Orthopedic Foot and Ankle Society Score (AOFAS) after 1 month from the end of treatment. Each measure of AOFAS is comprised of nine questions and covers three categories: Pain (40 points), function (50 points), and alignment (10 points). These are all scored together for a total of 100 points.[18,19]

Endpoints

The primary endpoint of the study was the pain control measured by NRS during every session of HESWT with peripheral block.

The secondary endpoints were the efficacy of HESWT 1 month after the end of treatment evaluated by AOFAS score, and the number of patients able to complete all planned sessions of shock wave treatment.

Statistical Analysis

Due to the lack of clinical studies that evaluate the efficacy of US-guided analgesic technique during High-Energy Shock Wave application, this study should be considered as a pilot one. Power analysis was based using data from the study of Klonschinski et al.[15] and reporting the reduction in NRS during HESWT from baseline (HESWT without anaesthesia) to first treatment with application of UPTNB of 40% (from 7 to 3 points) coupled with the highest estimate of Variance (SD, 4 points). The sample size calculated was 21 patients in the study group. The α and β errors for the sample size were chosen as 0.05 and 90%, respectively. Data distribution was assessed with the Kolmogorov–Smirnov test. Continuous variables with normal distributions were expressed as means and standard deviation (SD) and assessed with the Student t-test. Those with non-normal distributions were expressed as medians and interquartile ranges (IQR) and assessed with the Mann–Whitney test. Qualitative data are expressed as a number of events (%). The analysis of variance for repeated measures during the study was performed by one-way analysis of variance. When detected, post hoc analysis was performed using Bonferroni Test. The proportion of subjects able to complete each session of treatment was compared via Chi square test for equal proportion or Fisher exact test where numbers were small with results presented as the number and percentage. $P \leq .05$ were considered statistically significant. Statistical analysis was performed using MEDcalc (MedCalc Software Ltd, Belgium) version 18.6.

Results

Forty patients were scheduled in the study period for HESWT. Among them, 11 patients underwent the treatments without peripheral block, while 29 patients interrupted the first HESWT session for moderate-severe pain and were enrolled in the study (Figure 2). Eight patients were excluded from the analysis due to: Foot or ankle arthrosis, confirmed by X-ray diagnosis (four patients), allergy to local anaesthetic (two patients), and neurologic abnormality (two patients). Twenty-one patients were definitely enrolled.

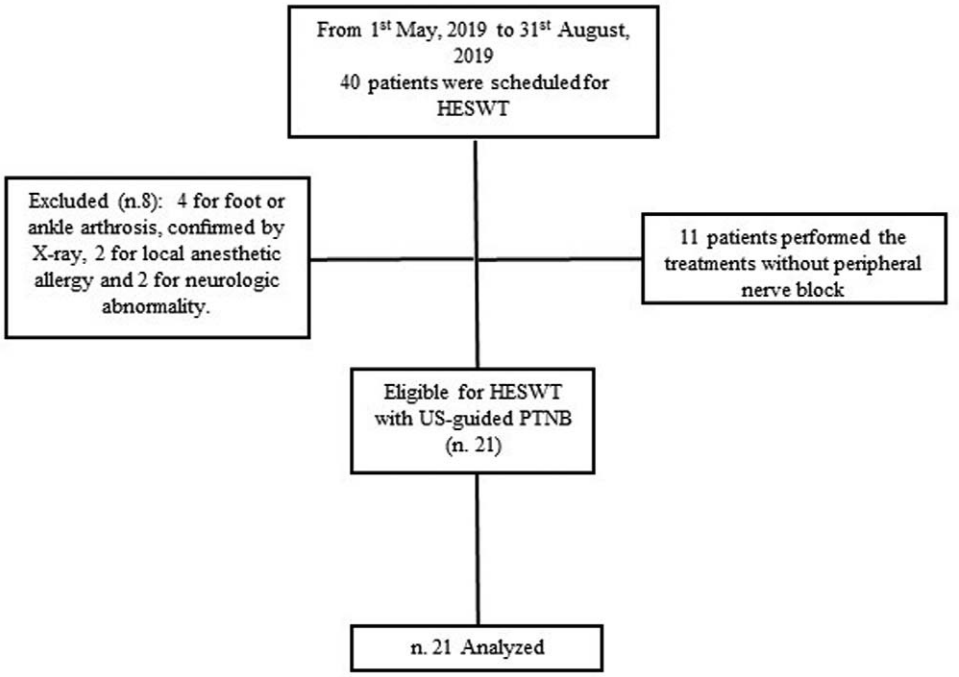

Figure 2. Study flow diagram.

Table 1. Patients Characteristics and Comorbidities and Type of Approach for HEWST Procedure.

	n = 21
Age (yr)	50.5 ± 11.7
Weight (kg)	70.6 ± 10.9
Height (cm)	162.9 ± 6.2
Sex (Female/Male) (n)	15/6
HEWST—Unilateral approach (%)	71
HEWST—Bilateral approach (%)	29
Comorbidity	
Hypertension (n)	7
FAP (n)	1

Note: Data are expressed as mean and standard deviation, and n or %. Abbreviations: FAP, paroxysmal atrial fibrillation; HESWT, high-energy shock wave therapy.

Table 1 shows the baseline characteristics of patients. Twelve patients presented ASA physical status I, while nine patients showed ASA physical status II. HESWT was applied in unilateral side in 15 patients and in bilateral sides in 6 patients.

Primary Outcome

US-guided PTNB showed a significant reduction of NRS score ($P < .01$) between the first HESWT without anaesthesia and the subsequent treatments under peripheral block (Figure 3). At the end of every HESWT session, all patients were able to walk and were discharged immediately from the hospital.

Secondary Outcomes

The application of US-guided PTNB allowed to split HESWT in all patients included in the study into only three applications, 1 every 2 weeks, giving on average 1800 shots of focussed shock wave with an energy of 0.25 mJ mm^{-2} at a frequency of 2.3 Hz. All patients completed the treatment sessions, receiving all the scheduled mJ mm^{-2} doses. HESWT determined a significant improvement of AOFAS score between the start of HESWT up to one month after the end of HESWT (44 [IQR: 44-51.25] vs 87.5 [IQR: 80-98.5] points, $P < .001$). HESWT was efficacious in pain relief after one month from the application of high-energy shock waves in all patients with plantar fasciitis.

Adverse Events

No side effects were found during the therapy sessions. After 1 month from the HEWST, no patients showed neurological or infectious complications.

Discussion

The execution of US-guided PTNB, during HESWT for painful foot diseases in an outpatient setting, significantly

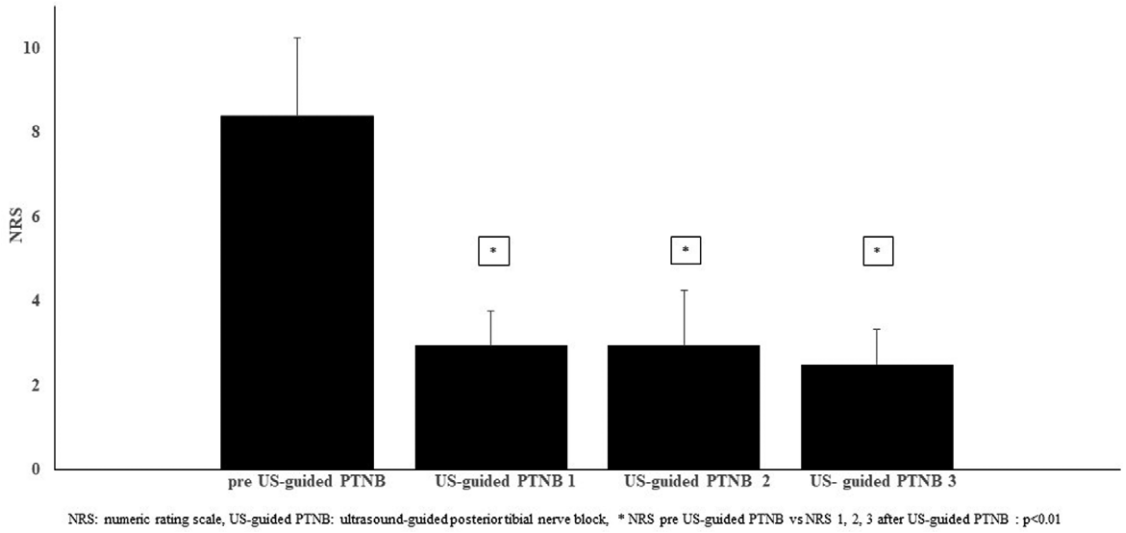

Figure 3. Effects of US-guided PTNB on pain intensity during high-energy extracorporeal shock wave therapy.
Note: The image illustrates the pain trend assessed by numeric rating scale (NRS) during the first application of high-energy shock wave therapy (HESWT) without the execution of US-guided posterior tibial nerve block (PTNB) and the subsequent treatments of HEWST with the execution of US-guided PTNB. * NRS pre US-guided PTNB vs NRS 1, 2, 3 after US-guided PTNB: *P* < .01.

reduced the intensity of pain when compared with the application of HESWT without peripheral nerve block. Moreover, it allowed patients to complete all shock wave plan in only three sessions, in comparison with the six sessions routinely performed in our Hospital for HESWT without analgesia. HESWT guaranteed a significant improvement of AOFAS score at 1 month after the end of therapy. This is in accordance with the majority of the current literature,[11,14] even if few randomised studies were not able to show any improvement.[10,20] Furthermore, the adjunct of US-guided PTNB apparently did not negatively interfere with the effectiveness of the treatment.

Accordingly, these results implied that the execution of US-guided PTNB during HESWT increased the patient's tolerance to the treatment with shock waves, reduced the number of treatment sessions, and was not associated with an increase in complications related to the peripheral block. In fact, all the patients scheduled for the study were discharged from the hospital immediately after the end of all the shock wave sessions.

In this specific clinical setting, the analgesic choice of PTNB allows, through the three main branches of the posterior tibial nerve (calcaneal, medial and lateral plantar), to obtain a satisfactory pain control of the areas (heel and sole of the foot) exposed to shock waves for the treatment of foot diseases.

Recent reviews[9,21,22] provided an overview of the recently published randomised clinical trials regarding the efficacy of shock wave therapy in patients affected by plantar fasciitis. The randomised clinical trials analysed in these reviews have demonstrated that shock wave therapy seems to be particularly effective in relieving pain. Therefore, shock wave therapy should be recommended for patients not responders to conservative therapy.

Unfortunately, the pain associated with the application of shock wave therapy (especially if high energy is applied) often reduces the patient's tolerance to shock wave treatment and causes the early interruption of therapy plan. This determines the refusal of the treatment and prompts the choice of alternative approaches, such as physical strategies and complementary and less used strategies.[23]

To date, few studies[10,11,14,15] have been performed to evaluate the efficacy of local or locoregional analgesia during HESWT in terms of pain control and long-term effectiveness of shock wave therapy in patients with plantar fasciitis. Our results are in line with a randomised control trial, by Kudo et al.,[11] who randomised 114 patients in two groups (a treatment consisting approximately of 3,800 total shock waves and a cumulative energy delivery of 1,300 mJ mm^{-2} in a single session vs placebo treatment). During this trial, all patients received the medial calcaneal nerve block with 5 mL of xylocaine 1% without the interference of locoregional analgesia on the effectiveness of shock wave treatment.

On the contrary, Haake et al.[10] randomised 272 patients with chronic plantar fasciitis refractory to conservative therapy, in two groups (135 patients have been allocated for

extracorporeal shock wave therapy and 137 patients have been allocated for placebo). All patients in this trial received the local infiltration with 2 mL of mepivacaine 1% on site of shock wave application. The authors showed no significant differences in terms of success rate, 12 weeks after intervention based on the Roles and Maudsley score.

Anyway, despite the results of these studies, the application of local anaesthesia (as local infiltration on treatment site, or calcaneal block or topical anaesthetic creams) is highly controversial during HESWT, mostly after the recent findings of some studies[14,15] that pointed out the negative effects of local anaesthesia application on HESWT effectiveness.

In fact, in a prospective randomised controlled trial, Rompe et al.[14] evaluated the influence of local anaesthesia on the efficacy of repetitive low-energy shock wave therapy for patients with plantar fasciitis. Of 86 patients enrolled in the study, 45 patients received low-energy shock wave therapy without anaesthesia and 41 patients received the treatment with infiltration of mepivacaine 1% 4 mL into the most tender area at the origin of the proximal plantar fascia on the medial calcaneal tuberosity. The authors concluded that the local anaesthesia applied prior treatment reduced the efficacy of shock wave therapy.

The molecular mechanisms underlying this phenomenon are unclear. An intriguing hypothesis evoking a possible primary role of local anaesthetics on the peripheral nervous system that would interfere with the shock wave applied to the musculoskeletal system, was suggested.[24–26] Klonschinski et al.[15] showed that the application of topic lidocaine cream on the treatment site prior the execution of low-energy shock wave therapy alters the biological response to shock wave therapy, preventing the activation and sensibilisation of nociceptive C-fibres.

To the best of our knowledge, this is the first clinical study exploring the clinical benefits associated with the application of a specific peripheral nerve block technique (different from local infiltration of shock wave site, calcaneal nerve block at the ankle or application of topic anaesthetic cream) during HESWT in outpatients affected by plantar fasciitis.

In accordance with the current minimally invasive analgesic approach and early discharge suggested by Enhanced Recovery After Surgery protocols,[27] all outpatients treated with US-guided PTNB during HESWT could be quickly discharged from the Hospital without pain or walking difficulties.

The execution of US-guided PTNB, in all patients who do not tolerate the HESWT due to moderate-severe pain, would extend the treatment to more outpatients, shortening the plan of treatment with a positive cost-effectiveness balance.

We acknowledge that this study has some limitations. First, this was not a randomised control trial. In fact, this study may be considered a pilot one due to the lack of clinical studies in this field. Second, this was a single centre study with a small sample size. Third, the aim of study was to evaluate the effects of a specific locoregional analgesia approach without analysing the comparison with others analgesic techniques.

US-guided PTNB proved to be a valid support for HESWT for plantar fasciitis in outpatient setting, allowing to reduce the pain intensity during the procedure, to minimise the patient discomfort, and to give the therapeutic doses only in three sessions. This specific US-guided locoregional analgesia approach did not seem to influence the effectiveness of HESWT after 1 month from the end of the treatment, unlike other analgesic techniques. Further studies should be warranted to verify the efficacy of US-guided PTNB in modifying the doses and pattern of treatment, its possible effect on the final pain relief and hospital costs.

Ethics Committee approval: Ethics committee approval was received from the ethics committee of Policlinico Universitario Agostino Gemelli IRCCS, Rome, Italy (approval number: 23234/19).

Informed Consent: Written informed consent was obtained from who participated in this study.

Author Contributions: Design - A.C., M.R.; Data Collection and/or Processing - G.S., G.F.; Analysis and/or Interpretation - G.S., G.F., A.C., A.V., C.C., N.C., M.S.; Critical Reviews - M.R., A.C., G.S., A.V.

Conflict of Interest: The authors have no conflicts of interest to declare.

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