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SHOCK-WAVE THERAPY SUCCESSFULLY TREATS FINGER ULCERS IN SCLERODERMA PATIENTS

SAN DIEGO – Extracorporeal shock-wave therapy at low energy levels showed promise as a new treatment for digital ulcers in patients with systemic sclerosis, or scleroderma, according to new research findings presented this week at the 2017 ACR/ARHP Annual Meeting in San Diego.

[Systemic sclerosis](#), also called scleroderma, is a serious and rare autoimmune disease that affects the skin and other organs. Severe complications may include kidney disease, pulmonary arterial hypertension (PAH), lung inflammation or gastrointestinal problems.

Systemic sclerosis (SSc) patients often have Raynaud's phenomenon as a complication, which can cause digital skin ulcers. Treatments like immunosuppressants, vasodilators or anticoagulants are often ineffective for digital ulcers and are associated with high costs and significant side effects. Low-energy, extracorporeal shock-wave therapy (ESWT) is effective at stimulating growth factors and the formation of new blood vessels, and healing these skin wounds, so a group of researchers in Japan conducted a study to test the effectiveness of this therapy.

“Digital ulcers are a severe complication of SSc caused by microvascular impairment and persistent vasospasm associated with Raynaud's phenomenon. Several studies have shown that approximately 50 percent of SSc patients experience digital ulcers. Ten percent require continuous therapy, and one percent exhibit severe symptoms such as gangrene,” said Tomonori Ishii, MD, a researcher at Tohoku University Hospital in Sendai, Japan and a lead author of this study. “In some cases, digital ulcers cause severe scarring and lead to amputation. Although most of the small ulcers are localized to the fingertips, some large ulcers spread throughout the finger and lead to necrosis or progressive digital shortening. Even a small fingertip ulcer causes severe pain and restricts activities of daily living.”

The study included 60 SSc patients with refractory digital ulcers who had no response to intravenous prostaglandin E1 therapy for at least four weeks. Thirty patients were treated with ESWT, while the other 30 patients were treated with currently available therapies. Patients in the ESWT group were allowed to continue their pre-study treatments as well. Patients were evaluated after eight weeks of therapy.

Results of the study showed a significant decrease in the number of ulcers in the ESWT group compared with the conventional treatment group (a mean of 4.47 versus 0.83, respectively) after eight weeks. In addition, 70 percent of the patients in the ESWT group experienced a decrease in the total number of their digital ulcers after eight weeks, compared to 26.7 percent of the patients in the conventional treatment group.

During the follow-up period, an average of 1.57 new ulcers formed in patients from the conventional treatment group, compared with 0.23 new ulcers for those treated with ESWT. The patients in the ESWT group reported no serious adverse events in association with the therapy during the eight-week study.

The researchers concluded treatment with ESWT is minimally invasive, well tolerated, does not require anesthesia and can result in clinically meaningful improvement for SSc patients with refractory digital ulcers.

“Low-energy ESWT may be a new approach to managing digital ulcers associated with SSc. ESWT has a strong and rapid effect for ulcer healing. It also has potential and unexpected benefits. First, ESWT may be effective in treating the pathology. It aims to stimulate neovascularization and is not intended to dilate damaged vessels,” said Dr. Ishii. “It is a non-pharmacological treatment that may avoid the adverse effects that are inevitable with medication. It can be used in patients with severe disease, including renal, cardiac, and respiratory failure, as well as gastrointestinal tract disturbances. Moreover, its safety may enable treatment repetition with efficacy. In addition to treating ulcers, ESWT may help eliminate pain, which is the most severe and persistent complaint of these patients.”

About the ACR/ARHP Annual Meeting

The ACR/ARHP Annual Meeting is the premier meeting in rheumatology. With more than 450 sessions and thousands of abstracts, it offers a superior combination of basic science, clinical science, tech-med courses, career enhancement education and interactive discussions on improving patient care. For more information about the meeting, visit <https://www.rheumatology.org/Annual-Meeting>, or join the conversation on Twitter by following the official #ACR17 hashtag.

About the American College of Rheumatology

The American College of Rheumatology is an international medical society representing over 9,400 rheumatologists and rheumatology health professionals with a mission to empower rheumatology professionals to excel in their specialty. In doing so, the ACR offers education, research, advocacy and practice management support to help its members continue their innovative work and provide quality patient care. Rheumatologists are experts in the diagnosis, management and treatment of more than 100 different types of arthritis and rheumatic diseases. For more information, visit www.rheumatology.org.

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Non-Randomized Controlled Trial to Evaluate the Effect of Extracorporeal Shock Wave Therapy on Digital Ulcers in Systemic Sclerosis

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Background/Purpose: Patients with systemic sclerosis (SSc) often display Raynaud's phenomenon, which causes digital skin ulcers. Since these ulcers are not associated with autoimmune factors, conventional immunosuppressive therapies, vasodilators, and anticoagulants are often ineffective. Extracorporeal shock wave therapy (ESWT) at low energy is shown to be effective in stimulating numerous growth factors endogenously, inducing angiogenesis and healing of injuries and wounds. This study evaluated ESWT for treatment of refractory skin ulcers caused by SSc and assessed its efficacy and safety.

Methods: We enrolled 60 patients with SSc and refractory digital ulcers with no response to intravenous prostaglandin E1 therapy at least 4 weeks. Of these, 30 were treated with ESWT and 30 received conventional treatment. Patients in the conventional treatment group were permitted to use any currently available therapies. Patients in the ESWT group continued pre-study treatments.

Results: The mean decrease in the number of ulcers at 8 weeks was 4.47 in the ESWT group and 0.83 in the conventional treatment group and the difference was significant ($p < 0.0001$). The proportion of subjects whose total number of ulcers decreased by 70% or more at 8 weeks was 26.7% in the conventional treatment group and 70.0% in the ESWT group and this was also significant ($p < 0.0008$). The average number of new ulcers in the 8 weeks after the start of treatment was 1.57 in the conventional group and 0.23 in the ESWT group. No serious adverse events associated with ESWT were reported during the study period.

Conclusion: After 8 weeks, ESWT demonstrated clinically meaningful improvement in SSc patients with refractory digital ulcers. This treatment is well-tolerated and minimally invasive, can be repeated without adverse effects, and requires no anesthesia. Overall, the results of our study suggest that ESWT is a novel and efficacious treatment that can be added to pharmacologic therapy.

Disclosures: **T. Ishii**, Chugai, Ono, Pfizer, Mitsubishi-Tanabe, Astellas, **Y. Kawaguchi**, None., **O. ishihawa**, None., **N. takasaawa**, None., **T. kodera**, None., **H. yasuoka**, None., **Y. takahashi**, None., **O. takai**, None., **I. Nakaya**, None., **H. Fujii**, None., **Y. Kamogawa**, None., **Y. Shirota**, None., **T. Shirai**, None., **Y. Fujita**, None., **S. saito**, None., **H. Shimokawa**, None., **H. Harigae**, None.