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Original Article

Therapeutic effects following extracorporeal shock wave therapy for insertional and non-insertional Achilles tendinopathy

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ABSTRACT

Background: The treatment for Achilles tendinopathy varies widely, and there is no consensus regarding the optimal treatment for both non-insertional and insertional Achilles tendinopathy. The purpose of this study was to evaluate the clinical efficacy of extracorporeal shock wave therapy (ESWT) in the treatment of insertional and non-insertional Achilles tendinopathy (AT).

Methods: Sixty patients with AT were invited to participate in this study. Patients were allocated to one of two groups according to the site of the AT, including an insertional AT (IAT) group and a non-insertional AT (NIAT) group. ESWT was performed once a week for five weeks for both groups. The Victorian Institute of Sport Assessment-Achilles questionnaire (VISA-A) score and the visual analog scale (VAS) were used five times to evaluate the clinical outcomes, including before treatment, immediately after treatment, as well as one month, three months, and five years after treatment.

Results: At three months after treatment, the IAT group exhibited a significantly higher VISA-A score (82 ± 6 *vs.* 76 ± 11; $p = 0.01$) and a significantly lower VAS score (1 ± 1 *vs.* 2 ± 1; $p < 0.001$) when compared with the NIAT group. At the five-year assessment, the IAT group (1 ± 1) had a significantly lower VAS score than the NIAT group (2 ± 1) ($p = 0.02$), while no significant difference for the VISA-A score was observed between the groups (84 ± 8 *vs.* 84 ± 10; $p = 0.98$).

Conclusions: Extracorporeal shock wave treatment can improve the symptoms of both insertional and non-insertional AT. The IAT patients experienced better clinical outcomes compared with the NIAT patients.

1. Introduction

Achilles tendon tendinopathy is a troublesome problem that affects both athletes and non-athletes. It is a considerable challenge to manage Achilles tendinopathy (AT) successfully.[1–3] In a previous investigation that included 697 patients, 5.6% of the patients had AT (4% insertional, 3.6% non-insertional, 1.9% both forms).[4] According to the anatomical location, AT has been subdivided into insertional and non-insertional tendinopathy.[5] Insertional AT (IAT) is a common problem, with the typical presentation being posterior heel pain at the insertion of the Achilles tendon onto the calcaneus.[6] Mid-portion AT or non-insertional AT (NIAT) is accompanied by pain and impaired function in the Achilles tendon.[7]

The treatment for AT varies widely, and there is no consensus regarding the optimal treatment for both IAT and NIAT.[8–12] Extracorporeal shock wave therapy (ESWT) is a widely accepted and effective treatment option for AT.[13–15] A previous study reported that the theories of the effects produced by ESWT could essentially be divided into pain relief, tissue regeneration, and destruction of calcifications.[16] ESWT has become one of the main treatments for IAT, particularly when other nonsurgical treatments have failed.[17] Shock wave therapy also has been reported to be an effective treatment for chronic NIAT.[18] Given that these conditions involve different anatomical locations, it was interesting to determine if there was a difference in the resulting clinical outcome between IAT patients and NIAT patients after undergoing ESWT.

Therefore, the aim of this study was to evaluate and compare the clinical efficacy of ESWT in treating the Achilles tendon between

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IAT and NIAT patients and including a long follow-up period. It was hypothesized that IAT patients would experience a better functional outcome than NIAT patients after ESWT.

2. Materials and methods

2.1. Study design

This study was approved by the Health Sciences Institutional Review Board of Huashan Hospital Fudan University. Consecutive AT patients experiencing pain for greater than six months were invited to participate in this study.

The diagnosis of AT was made by a specialist based on the patient's medical history, symptoms, and imaging. Each patient experienced localized pain at the Achilles tendon caused by overuse, trauma, degeneration, or other factors. Generally, the patients experienced tenderness on both sides of the Achilles tendon in the early stage of the condition. In the later stage, fusiform swelling of the Achilles tendon often appeared, accompanied by recurring pain and swelling. When the symptoms became aggravated, pain occurred when the patient walked or even flexed and extended the ankle joint without bearing weight on the affected limb. MRI or ultrasonography revealed degeneration of the Achilles tendon.

Based on the symptomatic region, the patients were divided into two groups, including an insertional group (insertion region AT, with the painful site within 2 cm from the calcaneal insertion) and a control group (mid-portion AT, with the pain in the site 2–6 cm from the calcaneal insertion).

Before the first ESWT session was conducted, baseline measurements of clinical function and ultrasonography were recorded for each patient. Follow-up examinations were performed immediately after treatment, at one and three months, and five years after treatment.

The inclusion criteria for the study were as follows: (1) AT was diagnosed, (2) no other treatments (such as drugs, physiotherapy, and others) were given during the extracorporeal shock wave treatment period, and (3) successful completion of a course of extracorporeal shock wave treatment. The exclusion criteria included (1) the presence of gout, ankylosing spondylitis, or other concurrent diseases, (2) the presence of high-arched feet or an ankle joint valgus deformity, and (3) the presence of peripheral neuropathy or systemic neurological disease.

2.2. Shock wave therapy

A radial shock wave device (EMS Swiss Dolor-Clast) was used to perform the shock wave therapy (Fig. 1). The number of impacts was 2,000, the energy density was 0.16 mJ/mm2, the pressure was 1.5–2.5 pa according to the patients' pain tolerance, and the frequency was 6~8hz. The shock waves were focused on the most distinctly painful portion of the Achilles tendon initially, and then the application was extended in a circumferential pattern. The hand-held pressure of the device was adjusted according to the patient's pain tolerance. The use of the device started in the area of maximal tenderness. The therapy was administered once a week over five weeks as a course of treatment.

2.3. Clinical evaluation

The clinical functional evaluation included the Victorian Institute of Sports Assessment-Achilles (VISA-A) questionnaire and the visual analog scale (VAS). The VISA-A questionnaire is a valid and reliable method of measurement of the severity of AT. The VISA-A score contains eight questions covering the three domains of pain, function, and activity (with a maximum score of 100).[19] These assessments were administered immediately before the treatment was initiated to establish the baseline, immediately after completion of treatment, at one and three months, and five years after treatment.

2.4. Ultrasonographic examination

Based on a previous report, all patients underwent ultrasonography scans (Philips Medical Systems, Bothell, Washington, USA) to determine whether calcification and neovascularization were present in the AT site (Fig. 2).[20] Neovascularization was determined based on the appearance of vessels inside the tendon.[21] If a calcified plaque was observed in the Achilles tendon, the maximal diameter of the calcified plaque was measured.

2.5. Statistical analysis

Data analysis was performed using Stata 10.0 software (Stata Corp, USA). The data were reported as means and standard deviations. A post-hoc power analysis was performed based on the VISA-A score. If a difference between the groups of at least 10 points was observed in the VISA-A, this was considered significant in the VISA-A. Given the standard deviation (SD) of the VISA-A score that was observed in the data, a sample size of at least 20 patients in each group was sufficient to identify a difference of 10 points in the VISA-A at a power of 0.80. Spearman's correlation coefficients were calculated between the VAS and different factors, including age, BMI, gender, calcification, and others. A $\chi 2$ test was used to compare the categorical variables. A two-sample *t*-test or two-sample Wilcoxon rank-sum test was used to compare the continuous variables between IAT group and NIAT group. One-way

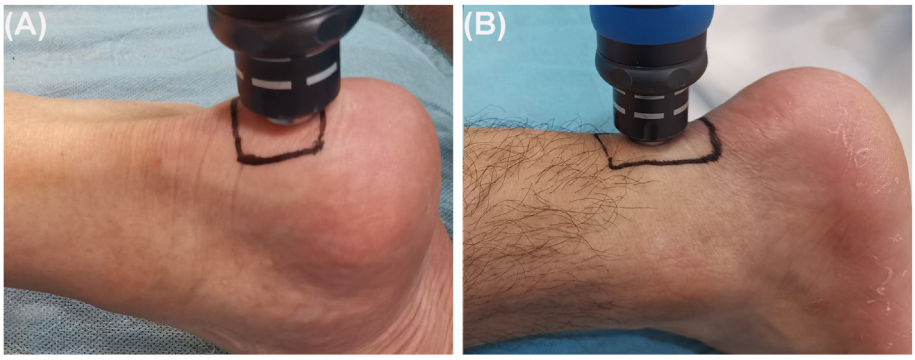

Fig. 1. Extracorporeal shock wave therapy in the treatment of insertional Achilles tendinopathy (A) and non-insertional Achilles tendinopathy (B).

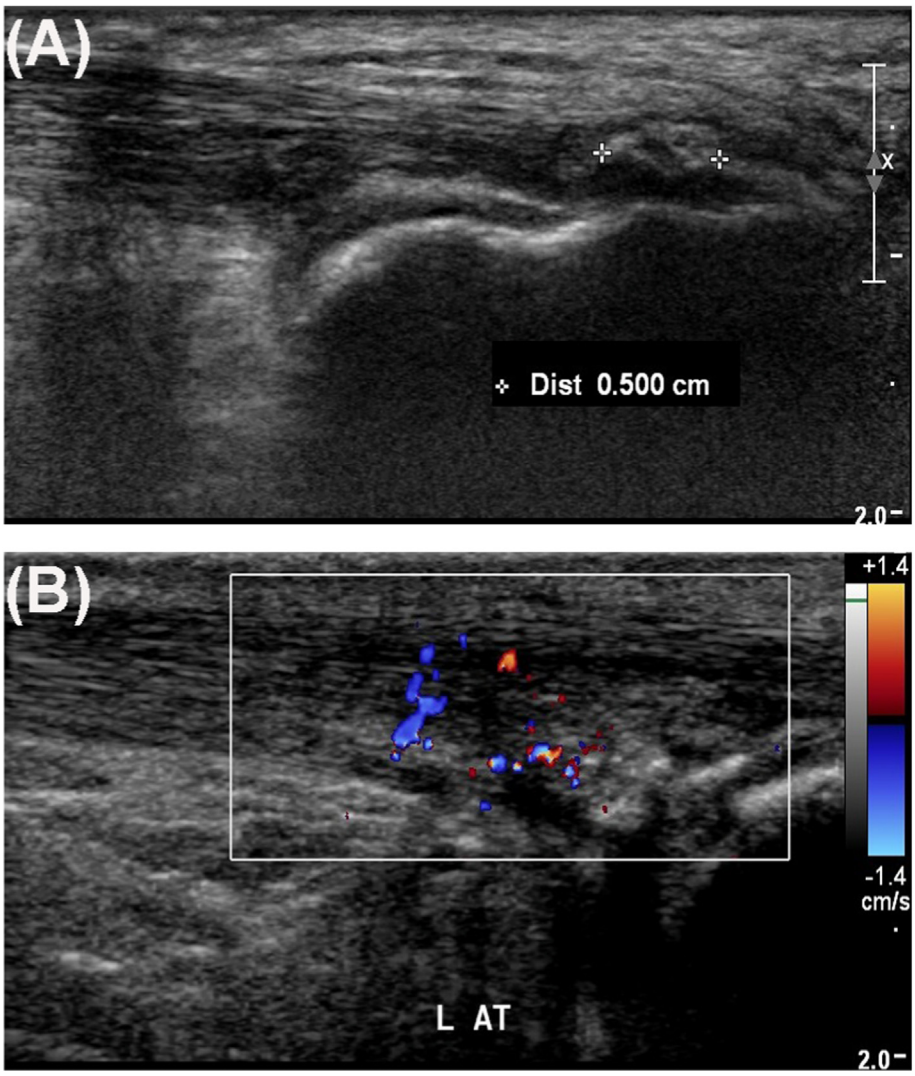

Fig. 2. Ultrasonographic examination of calcification (A) and neovascularization (B) in the Achilles tendon.

ANOVA followed by Bonferroni's post hoc test was used to compare the continuous variables among different timepoints. Statistical significance was set at $p < 0.05$.

3. Results

Throughout the entire follow-up time, no severe complications, including infection and tendon rupture, were observed in any of the patients included in the study. Collectively, 60 AT patients, including 35 IAT patients and 25 NIAT patients, agreed to participate in this study. The patients' demographic data was shown in Table 1. The two groups did not differ significantly with respect to age, body mass index (BMI), sex, symptom duration, degree of calcification, and degree of tendon neovascularization, as well as the VISA-A questionnaire or the VAS score before treatment.

All 60 patients were assessed immediately after the treatment ended and at one and three months after treatment. At five years after treatment, five patients (three IAT patients and two NIAT patients) were lost to follow up. In general, the VISA-A score increased over time (Fig. 3A), and the VAS decreased immediately after completion of the ESWT (Fig. 3B).

In the IAT group, the VISA-A score increased with time. There was a significant difference between baseline and zero timepoint ($p < 0.001$), between zero timepoint and one month timepoint ($p < 0.001$), between one month timepoint and three months timepoint ($p = 0.03$) respectively, while no significant difference of VISA-A was detected between three months timepoint and five years timepoint ($p = 0.99$). Moreover, the VAS decreased with time. There was a significant difference of VAS between baseline and zero timepoint ($p < 0.001$), while no significant difference of VAS was detected among other timepoints after treatment ($p > 0.05$).

In the NIAT group, the VISA-A score increased with time. There was a significant difference between baseline and zero timepoint ($p < 0.001$), while no significant difference of VAS was detected among other timepoints after treatment ($p > 0.05$). Moreover, the VAS decreased with time. There was a significant difference of VAS between baseline and zero timepoint ($p < 0.001$), while no significant difference of VAS was detected among other timepoints after treatment ($p > 0.05$).

When comparing the IAT and NIAT groups, there was no significant difference for VISA-A (69 ± 7 *vs.* 67 ± 10; $p = 0.26$) between groups. However, the IAT group had a significantly lower VAS than the NIAT group (2 ± 1 *vs.* 3 ± 1; $p < 0.001$) immediately after treatment (Fig. 4). At one month after treatment, the two groups exhibited comparable VISA-A scores (76 ± 6 *vs.* 73 ± 10; $p = 0.07$) while the IAT group (2 ± 1) still had a significantly lower VAS score

Table 1
Participant data of the study groups.

	IAT group (n = 35)	NIAT group (n = 25)	P value
Age, y	36 ± 11	36 ± 12	0.93
BMI (kg/m^2)	24 ± 2	24 ± 4	0.88
Female sex, n (%)	2 (6%)	6 (24%)	0.08
Duration of symptoms, mo	11 ± 5	11 ± 4	0.84
Sports-active, n (%)	21 (60%)	16 (64%)	0.75
Calcification, n (%)	19 (54%)	8 (32%)	0.09
Neovascularization, n (%)	11 (31%)	13 (52%)	0.11
VISA-A before treatment	53 ± 8	55 ± 8	0.46
VAS before treatment	7 ± 1	7 ± 1	0.94

BMI, Body mass index; IAT, insertional Achilles tendinopathy; NIAT, non-insertional Achilles tendinopathy.

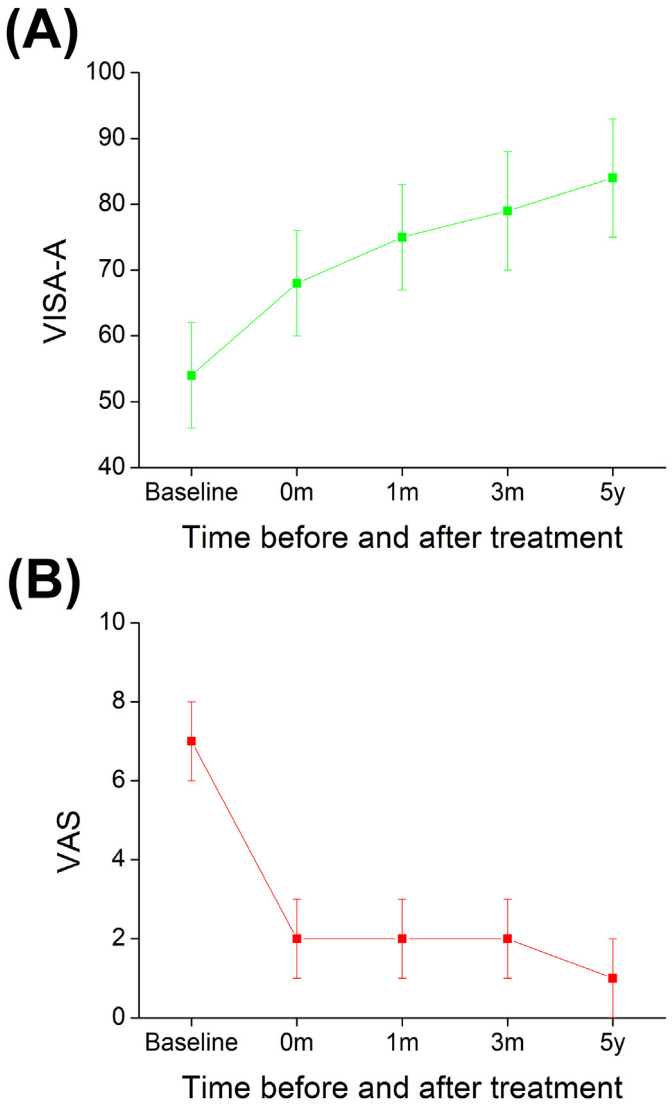

Fig. 3. Alternations of (A) VISA-A score; (B) pain VAS score. VISA-A, Victorian Institute of Sports Assessment–Achilles; VAS, visual analog scale.

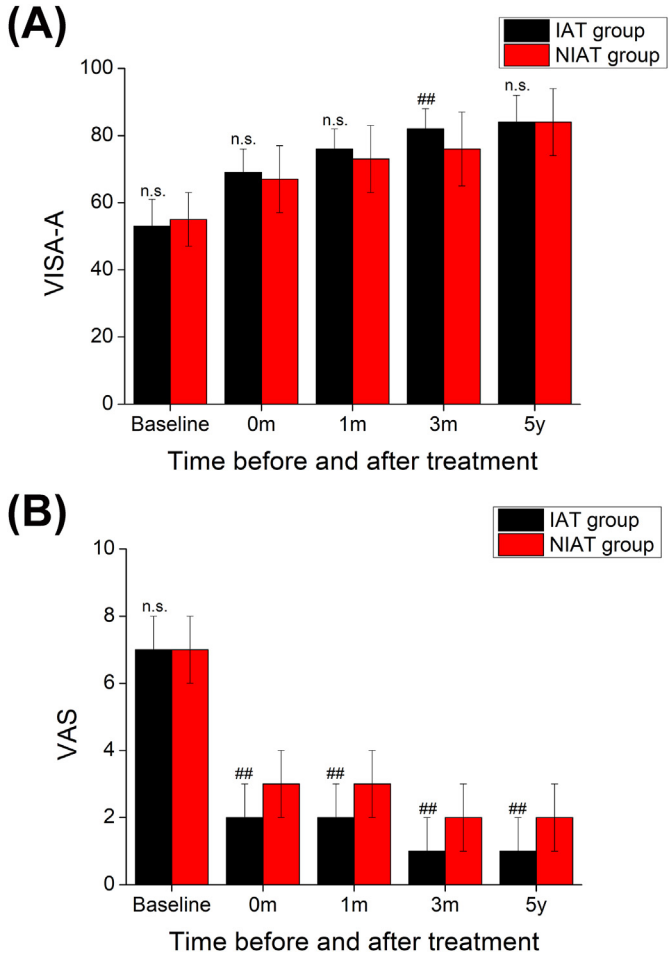

Fig. 4. Comparison of the VISA-A score (A) and pain VAS score (B) before and after treatment between the IAT group and the NIAT group. "##" indicates that there was a significant difference between the IAT group and the NIAT group. "n.s." indicates that there was no significant difference between the IAT group and the NIAT group. VISA-A, Victorian Institute of Sports Assessment–Achilles; VAS, visual analog scale; IAT, insertional Achilles tendinopathy; NIAT, non-insertional Achilles tendinopathy.

than the NIAT group (3 ± 1) (p < 0.001). At three months after treatment, the IAT group exhibited a significantly higher VISA-A score (82 ± 6 *vs.* 76 ± 11; $p = 0.01$) and a significantly lower VAS score (1 ± 1 *vs.* 2 ± 1; $p < 0.001$) compared to the NIAT group. At three months after treatment, 33 patients (94%) in the IAT group and 22 patients (88%) in the NIAT group were satisfied with the results ($p = 0.69$).

Interestingly, five years after treatment, 13 patients in the IAT group and eight patients in the NIAT group again experienced pain in their Achilles tendon. All of these patients accepted two or more sessions of ESWT treatment. At the five-year time, two patients (6%) in the IAT group and two patients (9%) in the NIAT group still experienced pain in their Achilles tendon ($p = 0.86$). Concerning the assessment scores, the IAT group (1 ± 1) presented a significantly lower VAS score than the NIAT group (2 ± 1) ($p = 0.02$), while no significant difference for the VISA-A score was observed

between the groups (84 ± 8 *vs.* 84 ± 10; $p = 0.98$). At the five-year assessment, 29 patients (91%) in the IAT group and 21 patients (91%) in the NIAT group were satisfied with the effect ($p = 0.70$).

Possible correlations between the VAS scores and different factors, including age, BMI, gender, symptomatic region, symptomatic duration, sports-activity type, calcification, and neovascularization, were analyzed in the IAT group and the NIAT group (Table 2). Concerning the IAT group, the VAS scores at five years were positively correlated with the sports-activity type ($p = 0.001$). With respect to the NIAT group, the VAS scores were positively correlated with age at one month after treatment ($p = 0.03$) and three months after treatment ($p = 0.01$).

All patients were examined using ultrasonography before treatment, and 38 patients underwent ultrasonography examination after treatment. Interestingly after treatment, no noticeable changes were observed in calcification (Fig. 5) or neovascularization (Fig. 6) based on the ultrasonography examination.

4. Discussion

The most important finding of this study was that the VISA-A score increased with time, and the VAS score decreased immediately after ESWT treatment. Furthermore, the IAT group exhibited better functional scores (a higher VISA-A and a lower VAS score) than the NIAT group after ESWT treatment. These findings indicated that shock wave treatment could improve the symptoms of AT. Moreover, the IAT patients experienced better clinical outcomes compared with the NIAT patients.

In general, there are several conservative treatments for AT, including shock wave, eccentric exercises, platelet-rich plasma (PRP) injection, and others.[22,23] In 2008, Rompe et al. demonstrated that low-energy shock-wave therapy and eccentric loading showed comparable results at 4-month follow-up.[24] Furthermore in 2008, Rompe et al. reported that eccentric loading showed inferior results to low-energy shock wave therapy as applied in patients with chronic recalcitrant tendinopathy of the insertion of the Achilles tendon at 4 months of follow-up.[25] In 2009, they revealed that a combination of eccentric loading and repetitive low-energy shock-wave treatment was better than eccentric loading alone chronic recalcitrant NIAT.[26] Compared with other methods, shock wave treatment has several advantages. It is easy to perform, relatively safe, economical, and non-invasive. In the present study, it was observed that the VISA-A score increased over time, and the VAS score decreased immediately after the completion of the shock wave treatment. Also, 13 patients in the IAT group and eight patients in the NIAT group experienced a recurrence of AT during the five years after treatment. They accepted shock wave treatment again, and most of them experienced recovery. Thus, ESWT appears to be beneficial for the long-term mitigation of pain and improved functional outcome in patients with refractory AT.[27]

In a study that analyzed 355 patients after shock wave treatment for the management of tendinopathies, Notarnicola et al. reported a success rate of only 54.9% two months after completion of ESWT treatment.[28] Moreover, Vulpiani et al. evaluated the effectiveness of ESWT in the symptomatic treatment of Achilles tendinopathies over time, and they observed satisfactory results in only 47.2% of cases two months after completion of ESWT treatment, but for 73.2% of the cases at medium-term (six to 12 months), and 76% of the cases at long-term (13–24 months).[29] In the present study, it was found that 29 patients (91%) in the IAT group and 21 patients (91%) in the NIAT group were satisfied with the effect five years after completion of ESWT treatment. These findings indicated that the extracorporeal shock wave could effectively treat AT disease even for a long time.

Previously, Notarnicola et al. reported that a high BMI and male gender were prognostic factors for improvement. In the present study, possible correlations between VAS and various factors were analyzed in the two patient groups.[28] It was found that the VAS score was positively correlated with the sports-activity type in the IAT group, while the VAS score had a positive correlation with age in the NIAT group. These findings indicated that there might be different pathology in IAT compared to NIAT. The IAT might occur due to overuse during sports activity, while the NIAT might occur due to degeneration. Also, Ryan et al. investigated the effect of dextrose injections in a large patient population at two years following treatment.[30] They observed that both midportion and insertional AT patients exhibited significant improvement in pain scores from baseline to follow-up for all VAS items, and the two groups seemed to have comparable VAS results at the follow-up assessment. Moreover, Wheeler et al. investigated 39 patients who underwent ESWT plus a home exercise program and found no significant differences in the outcomes for patients with insertional and non-insertional tendinopathy and a mean follow-up duration of 163 days.[31]

In the present study, a significant difference in the VAS score was observed between the IAT and NIAT groups. The reasons for this difference might be due to several factors. First, the painful area experienced by the NIAT patients was typically relatively large, while the painful region experienced by the IAT patients was more focused and concentrated as a single point. Giving the same time of shock wave therapy, the treatment for the NIAT appeared less satisfactory compared with the treatment for the IAT. Second, the pathologies for insertional tendinopathy and non-insertional tendinopathy were different. Apoptosis might play a role in the development of NIAT and appears to be related to the presence of elevated eNOS and iNOS levels.[32] The mid-portion section of the Achilles tendon is relatively ischemic and lacks neovascularization even after extracorporeal shock wave treatment.[33] Therefore, the recovery capacity for NIAT is more limited than that of IAT.

There are several limitations to this study. First, only 60 patients were investigated, which was a relatively small sample size. Further investigations need to be performed with a larger sample size to allow additional patient data. Second, no change in neovascularization was evident in the treated Achilles tendon at follow-up examination. Controversy persists concerning the effect of neovascularization on the treatment of the Achilles tendons. Third, histological analysis of the AT tissue could not be performed in these patients, which meant that the underlying reason for the tendinopathy was not determined definitively. Forth, muscle

Table 2
Possible correlations between VAS and various factors in the IAT and NIAT group.

Variable IAT Group	1 months		3 months		5 years	
	rho	P value	rho	P value	Rho	P value
Age	−0.12	0.48	−0.16	0.35	−0.20	0.27
BMI	0.16	0.36	0.20	0.26	−0.26	0.14
Gender	0.19	0.27	0.22	0.21	−0.05	0.76
symptomatic duration	−0.02	0.89	0.05	0.79	−0.19	0.31
sports-active type	0.16	0.36	0.13	0.45	0.70	0.001
Calcification	−0.14	0.41	−0.28	0.11	−0.05	0.79
neovascularization	−0.09	0.62	−0.25	0.14	−0.14	0.43
NIAT Group						
Age	0.45	0.03	0.49	0.01	0.14	0.51
BMI	0.13	0.53	0.24	0.23	0.24	0.27
Gender	−0.02	0.92	−0.21	0.32	−0.03	0.89
symptomatic duration	0.11	0.61	0.004	0.99	0.10	0.66
sports-active type	−0.29	0.16	−0.23	0.28	0.04	0.86
Calcification	0.16	0.44	0.21	0.32	−0.18	0.40
neovascularization	0.28	0.17	0.04	0.86	0.14	0.51

BMI, Body mass index; VAS, pain visual analog scale; IAT; IAT, insertional Achilles tendinopathy; NIAT, non-insertional Achilles tendinopathy.

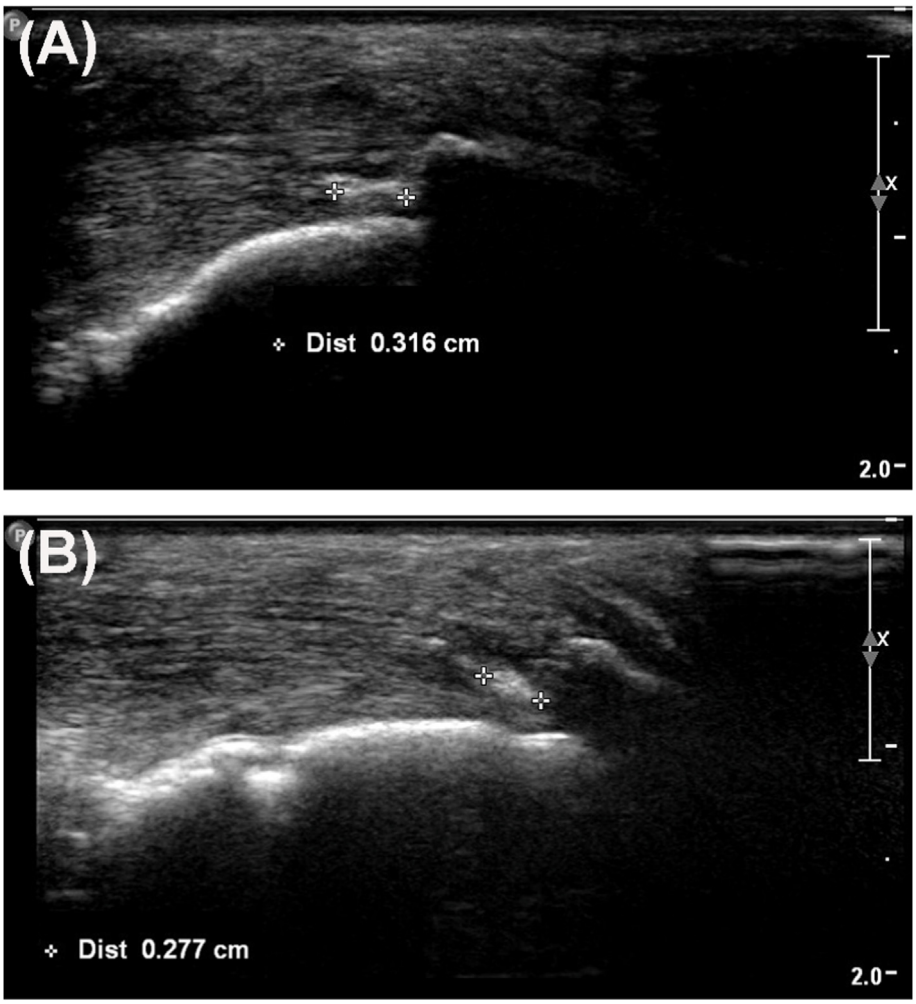

Fig. 5. Ultrasonography images revealed the calcification in the Achilles tendon before treatment (A) and after treatment (B). No obvious change of calcification was noted after treatment.

strength was not analyzed in the present study. Finally, we used radial shock wave device in the present study. It was unknown if there would be different results when a focused shock wave device was applied. Previously, a systematic review reported that there is no scientific evidence in favor of either radial ESWT or focused ESWT with respect to treatment outcome.[34]

5. Conclusion

In summary, extracorporeal shock wave treatment improved the symptoms of insertional and non-insertional AT, and the IAT patients experienced better clinical outcomes compared with NIAT patients.

Availability of data and materials

The datasets used and/or analyzed during the current study are not publicly due to patient privacy but are available from the corresponding author on reasonable request.

Authors' contributions

All authors contributed to the study and preparation of the manuscript. Planning of the study protocol were performed by YL and YH. Data collection and analysis were performed by HL with assistance of WY and XX. The first draft of the manuscript was written by HL and all authors commented on previous versions of the manuscript. All authors read and approved the final manuscript.

Ethics approval and informed consent to participate

All procedures performed in this study involving human participants were in accordance with the Declaration of Helsinki (as revised in 2013). The study was approved by the Ethics Committee of Huashan Hospital Fudan University. All participants in this study signed an informed consent prior to participation. The authors are accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

Consent for publication

Not applicable.

Declaration of competing interest

The authors declare that they have no competing interests.

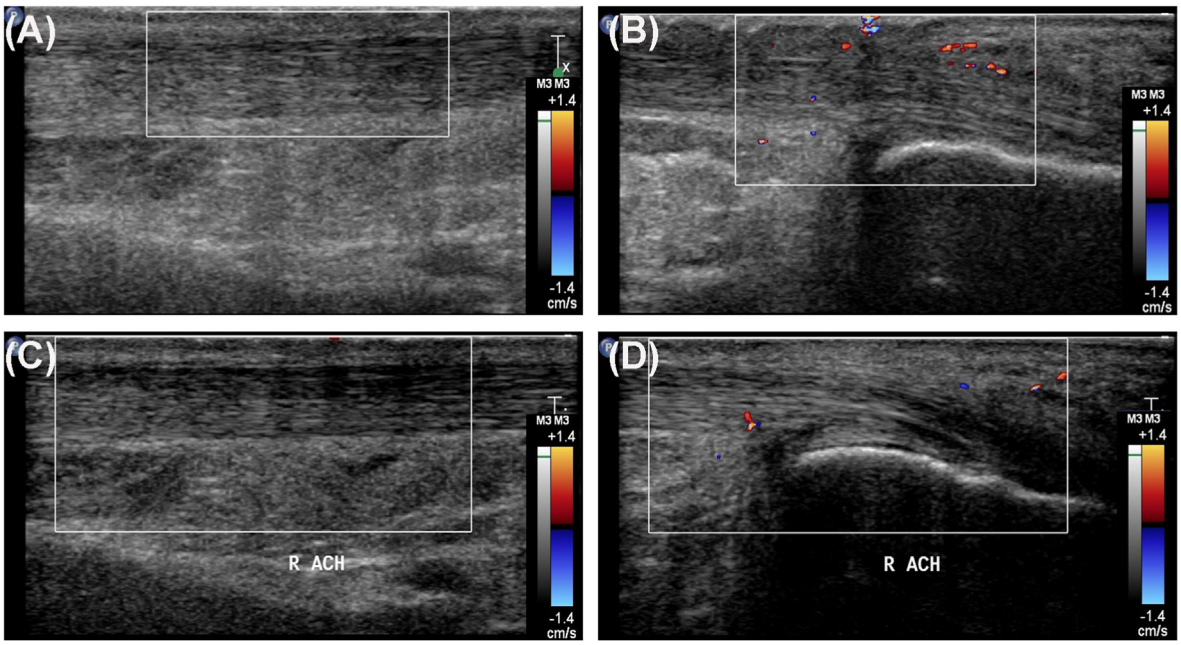

Fig. 6. Ultrasonography images revealed neovascularization in the midportion part (A, C) and the insertional site (B, D) of Achilles tendon before treatment (A, B) and after treatment (C, D). After ESWT therapy, no obvious increase of neovascularization was observed in the Achilles tendon. ESWT, extracorporeal shock wave therapy.

Acknowledgements

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Abbreviations

AT	Achilles tendinopathy
BMI	Body Mass Index
ESWT	extracorporeal shock wave therapy
IAT	Insertional Achilles tendinopathy
MRI	magnetic resonance imaging
NIAT	non-insertional Achilles tendinopathy
PRP	platelet-rich plasma
SD	standard deviation
VAS	visual analog scale
VISA-A	Victorian Institute of Sport Assessment-Achilles

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