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Original Article

Thread-embedding acupuncture may improve symptom resolution in patients with gastroesophageal reflux disease: A randomized controlled trial

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ABSTRACT

Background: Various traditional medicine treatments have been investigated to treat GERD. Among those, thread-embedding acupuncture (TEA) has the advantage that patients need to undergo the procedure infrequently; however, its efficacy is unclear. This study evaluated the efficacy of TEA in treating GERD.
Methods: A randomized controlled trial was conducted with 66 participants with GERD: 33 received two sessions of TEA + standard therapy (proton-pump inhibitor [PPI]) (TEA+PPI group) and 33 received PPI alone (PPI group). Primary outcomes included GerdQ score and heartburn and regurgitation resolution. Secondary outcomes were antacids requirement, the Frequency Scale for Symptoms of GERD (FSSG) score, and Gastroesophageal Reflux Disease-Health Related Quality of Life (GERD-HRQL) score. The safety outcome was adverse events (AEs).
Results: After four weeks of treatment, the TEA+PPI group significantly reduced the GerdQ score (mean difference [MD] and 95% confidence interval [CI]: -1.8 [-2.4, -1.1]) and increased the rate of heartburn and regurgitation resolution compared to PPI (54.5% versus 9.1%, respectively) compared to PPI. The TEA+PPI group also significantly reduced the number of antacid packs used (MD [95%-CI]: -9.4 [-12.1, -6.7]), FSSG score (MD [95%-CI]: -9.4 [-11.0, -7.8]), and GERD-HRQL score (MD [95%-CI]: -5.6 [-7.7, -3.5]) compared to PPI. Five patients experienced AEs, which were mild local complications at the acupoints.
Conclusion: TEA combined with PPI is more effective than PPI alone in treating GERD. Further studies with longer follow-ups are required to confirm these findings.
Clinical trials registration information: ClinicalTrials.gov, NCT05353933.

1. Introduction

The worldwide prevalence of GERD is approximately 13%, and with an increasing trend, GERD has become one of the most common diseases in the world.[1,2] Its symptoms significantly affect many aspects of life and reduced work productivity.[3] The typical symptoms of GERD are heartburn and regurgitation, but definitive diagnosis of GERD is difficult. The current treatment of GERD remains a challenge. The first-line treatment is a standard dose of proton-pump inhibitors (PPIs).[4] However, after four weeks of empiric PPI treatment, up to 50% of patients still have heartburn. After eight weeks of treatment, even with a double dose of PPI, up to 30% of patients are still resistant to the treatment.[5]

Traditional medicine (TM) treatments, including pharmacological and non-pharmacological methods, have shown effectiveness for GERD when combined with Western medicine (WM).[6] In addition, TM treatments can lower medical expenses for hospitalization and outpatient clinic care for peptic ulcer disease.[7] Among them, acupuncture is of great interest. A meta-analysis showed that acupuncture had a similar effectiveness to WM as a monotherapy, and the combination of acupuncture and WM had superior effectiveness and reduced the recurrence of

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GERD compared to monotherapy.[8] However, the fact that patients have to go to a health facility for acupuncture regularly can interfere with treatment compliance.

Thread-embedding acupuncture (TEA) is a type of acupuncture which involves selecting acupuncture points similar to those used in manual acupuncture and electroacupuncture. TEA has shown its safety and effectiveness in many diseases, such as epigastric pain, obesity, low back pain, leg pain, and psoriasis, especially in diseases that require long-term treatments.[9] An advantage of TEA is that patients only need to undergo the procedure every 1-2 weeks, whereas other acupuncture treatments are typically performed on a daily basis. A study showed that TEA was superior to WM in the treatment of GERD.[10] Nevertheless, the effect of the combination of TEA and WM has yet to be investigated. In this study, we evaluated the efficacy of TEA combined with standard therapy (PPIs) when compared with PPIs alone for GERD.

2. Methods

2.1. Trial design

This study is a single-center, assessor-blinded, randomized controlled trial. The study was performed from May 2022 to July 2022 at the University Medical Center Ho Chi Minh City – Branch 3. The protocol was registered with ClinicalTrials.gov, NCT05353933.

2.2. Ethical statement

The study was approved by the Ethics committee of the University of Medicine and Pharmacy at Ho Chi Minh City (No. 606/ HĐĐĐ-ĐHYD, dated November 16, 2021). Written informed consent was obtained from all participants before participating in the study.

The study was performed following the ethical principles of the Declaration of Helsinki and the International Conference on Harmonization-Good Clinical Practice guidelines, Consolidated Standards of Reporting Trials (CONSORT), and Standards for Reporting Interventions in Clinical Trials of Acupuncture (STRICTA) guidelines for designing and reporting trials.[11]

2.3. Participants

The study recruited patients with GERD in the outpatient department. All criteria were based on questions related to the medical history and physical examination. We did not perform an esophagogastroduodenoscopy for screening since this is an invasive procedure.

Inclusion criteria included: (i) men or women aged from 18 to 60 years, (ii) a GerdQ score of eight or above, (iii) having heartburn and/or regurgitation on two days per week or more.

Exclusion criteria were: (i) any conditions related to a structural disease that had been confirmed by any previous endoscopy; (ii) uncontrolled inflammatory bowel disease, chronic diseases, genetic diseases, or a history of alcohol or drug abuse; (iii) alarming symptoms that suggest gastric cancer, complicated ulcer disease, or other serious illnesses; (iv) history of esophageal or gastrointestinal surgery; (v) current use of drugs affecting treatment and evaluation of GERD; (vi) treatment with WM medications, or any TM methods for GERD in two weeks prior to randomization; (vii) history of hypersensitivity reaction with PPIs, antacid, catgut, acupuncture, or TEA treatment; (viii) pregnancy or breastfeeding; and (ix) current participation in any other clinical trials.

2.4. Randomization and blinding

Eligible participants were randomly assigned in a 1:1 ratio into either TEA+PPI or PPI group. Block randomization with a block size of six was prepared using SAS software version 9.4. The randomization codes were concealed using opaque seals envelopes with ordered numbers before allocation. Eligible patients were allocated to receive either TEA+PPI or PPI according to the sequential order of the recruitment.

Outcome assessors and data analysts were blinded to the treatment group allocation. One treating physician was not blinded to the group allocation but was not involved in the outcome assessments or data analyses. The patients were not blinded to the treatment they received.

2.5. Interventions

In both groups, all participants received the assigned treatments in four weeks. Standard therapy following the World Gastroenterology Organisation (WGO) 2017 guidelines was applied in both groups.[12] It included lifestyle changes, PPIs, and antacids when needed. The medicines were orally used, including pantoprazole (40 mg) once every day and 1-2 antacid packs consisting of aluminium oxide (400 mg) and magnesium hydroxide (800.4 mg) when having reflux symptoms (up to six packs per day). Lifestyle changes were consulted between the physician and participant with an information sheet. At the follow-up visits, the physician checked and reminded the treatment compliance of the participants.

In the TEA+PPI group, we added two sessions of TEA therapy at randomization and two weeks after randomization. The procedure was performed in a standard room for TEA by a TM physician with more than ten years of experience in TEA. The technique was based on the guidance of the Vietnamese Ministry of Health. The acupoints included Xiawan (CV10), Zhongwan (CV12), Shangwan (CV13), Zusanli (ST36), Neiguan (PC6), Geshu (BL17), Ganshu (BL18), Pishu (BL20) in both sides of the body. Zusanli, Zhongwan, Neiguan, Shangwan, and Xiawan have been commonly selected in treating GERD and regulating the lower esophageal sphincter.[13,14] Based on the affected organs in GERD and the shu-mu point combination (a principle of acupoint selection), we selected Ganshu, Pishu, and Zhongwan for the Liver, Spleen, and Stomach, respectively.[15,16] Finally, we chose Geshu, the Back-shu point of the diaphragm because it has been shown to regulate the diaphragm (which contributes to the mechanism of GERD) and descend counterflow Qi.[15] The location of the acupoints was determined according to the World Health Organization (WHO) standards (Supplement 1).[17]

The TEA was conducted with a 1-cm length of a 3/0 catgut chromic thread (absorbable sutures), except for the Neiguan point, we used a 0.5 cm thread. A 23-gauche disposable hypodermic needle was used to insert the threads (Supplement 1). First, we marked the acupoints using a surgical marker and performed local anaesthesia using lidocaine 10% spray. After five minutes, we disinfected the sites with an alcoholic povidone-iodine solution and performed the TEA. We inserted the needle perpendicularly into the acupoint with a depth of 1 to 1.5 cm, depending on the body area. In the Neiguan point, we inserted the needle with a direction of 45 degrees and a depth of 0.5 cm. We then pushed the thread into the body and withdrew the needle immediately.

2.6. Outcomes

The primary outcomes included GerdQ score and the resolution of the typical symptoms (heartburn and regurgitation) four weeks after randomization. GerdQ score was assessed using the GerdQ questionnaire to evaluate the severity of GERD. A higher score indicates a more severe condition.[18]

Secondary outcomes were antacids requirement, symptom frequency, health-related quality of life, and the safety of TEA. The antacid requirement was assessed by the number of antacid medication packs used per week during the 4-week intervention. Each pack contained aluminium oxide (400 mg) and magnesium hydroxide (800.4 mg). Participants were asked to record the number of antacid packs used in the previous week and report it to the treating physician at the follow-up visits. The symptom frequency was assessed using the Frequency Scale for the Symptoms of GERD (FSSG) every two weeks. A higher score indicates more severe symptoms.[19] The quality of life was assessed by the Gastroesophageal Reflux Disease-Health Related Quality of Life tool

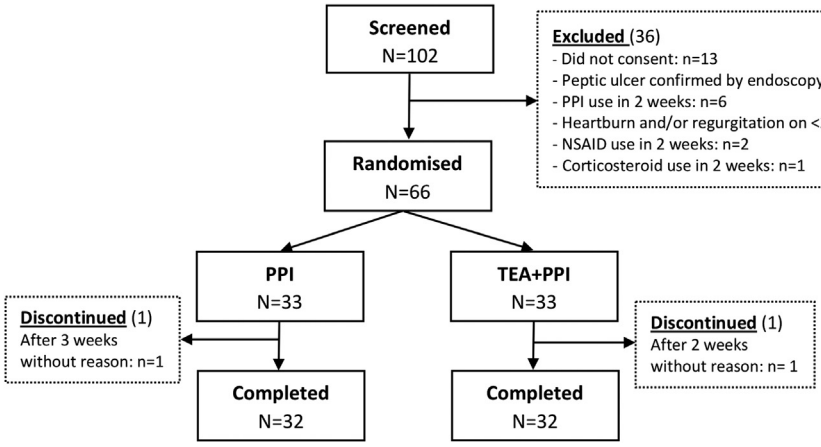

Fig. 1. Flow diagram of patient selection. NSAID, non-steroidal anti-inflammatory drug; PPI, proton-pump inhibitor; TEA, thread-embedding acupuncture.

(GERD-HRQL) every two weeks. The higher score indicates the worse impact of the disease on quality of life.[20]

The safety of TEA was assessed based on the adverse events (AEs) related to TEA. The treating physician identified the expected and unexpected AEs associated with the TEA.

2.7. Sample size calculation

The sample size was calculated to detect the difference in the treatment effect with a type-1 error of 0.05 and a type-2 error of 0.1, based on the primary outcome. According to a previous study, the rate of heartburn resolution after four weeks of a standard dose of PPIs was 50%.[5] We expected that the combination of PPI and TEA would raise this rate to 90% after four weeks of treatment, similar to a study on TEA.[10] The required sample size was 26 in each group. A sample size of 33 in each group was required to allow for a dropout rate of 20%.

2.8. Statistical analysis

All efficacy analyses were performed with an intention-to-treat (ITT) data set. The binary efficacy outcomes, including heartburn and regurgitation resolution rates, were presented as frequencies and percentages (%) with 95% confidence intervals (CIs). The difference between the two groups was tested by Fisher's exact test. The numeric efficacy outcomes, including GerdQ score, the number of antacid packets, FSSG and GERD-HRQL scores, were presented as median and interquartile range (IQR) and were tested for the difference between the two groups by Wilcoxon rank-sum test due to the non-normal distribution. Adverse event rates of TEA were presented as frequencies and percentages (%). The comparison between groups was expressed by risk ratio (RR) and 95% CI for binary outcomes and mean difference (MD) and 95% CI for numeric outcomes. Analyses were done using the statistical software R version 4.1.0. The significant level was set as a p-value of less than 0.05.

3. Results

Among 102 screened patients, 36 were not eligible to be randomized. Finally, 66 patients were randomized to the TEA+PPI (33 patients) and PPI group (33 patients). One patient in each group was lost to follow-up (Fig. 1).

3.1. Baseline characteristics

The baseline demographic and clinical characteristics of the randomized participants are shown in Table 1. In general, the baseline characteristics were balanced in the two groups.

Table 1
Baseline demographic and clinical characteristics.

	PPI (N = 33)	TEA+PPI (N = 33)
Sex male, n (%)	15 (45)	17 (52)
Age (year), median (IQR)	26 (22, 31)	26 (23, 36)
Occupation, n (%)		
Manual labor	2 (6.1)	2 (6.1)
Mental labor	28 (84.9)	29 (87.9)
No labor	3 (9.1)	2 (6.1)
Overweight/obesity, n (%)	3 (9.1)	2 (6.1)
Smoking, n (%)	3 (9.1)	4 (12.1)
Alcohol consumption, n (%)	5 (15.2)	4 (12.1)
Disease duration, n (%)		
<1 year	7 (21.2)	7 (21.2)
1-5 years	16 (48.5)	18 (54.6)
5-10 years	7 (21.2)	7 (21.1)
≥10 years	3 (9.1)	1 (3.0)
GerdQ score, median (IQR)	11 (10, 12)	11 (10, 12)
Reflux symptoms, n (%)		
Hearturn	33 (100)	33 (100)
Regurgitation	33 (100)	31 (93.9)
Having endoscopy prior to enrollment, n (%)	24 (72.7)	27 (81.8)
Results from endoscopy, n (%)*		
Non-erosive reflux disease	15 (62.5)	19 (70.3)
Mild reflux esophagitis (LA grade A/B)	4 (16.7)	6 (22.2)
Severe reflux esophagitis (LA grade C/D)	0 (0)	0 (0)
Unclassified reflux esophagitis	5 (20.8)	2 (7.4)

IQR, interquartile range; LA, Los Angeles classification; PPI, proton-pump inhibitor; TEA, thread-embedding acupuncture.

* The percentage is calculated based on the number of patients received endoscopy.

3.2. Primary outcomes

3.2.1. GerdQ score and GERD typical symptoms resolution

After four weeks of treatment, the TEA+PPI group significantly reduced the GerdQ score compared to the PPI group (MD [95% CI]: -1.8 [-2.4, -1.1]) (Fig. 2A, Supplement 2). The TEA+PPI also significantly increased the rate of the resolution of heartburn, regurgitation, and both of them (RR [95% CI] was 2 [1.3, 3.2], 2.7 [1.3, 5.6], and 6 [1.9, 18.4], respectively) compared to PPI alone (Fig. 2B, Supplement 2).

3.3. Secondary outcomes

3.3.1. Improvement of FSSG and GERD-HRQL scores and antacids requirement

After four weeks, the TEA+PPI group showed a significantly higher reduction in FSSG and GERD-HRQL scores than the PPI group. The MD (95% CI) was -9.4 (-11.0, -7.8) for the FSSG score and -5.6 (-7.7, -3.5) for the GERD-HRQL score (Fig. 2C, D, Supplement 2). The TEA+PPI

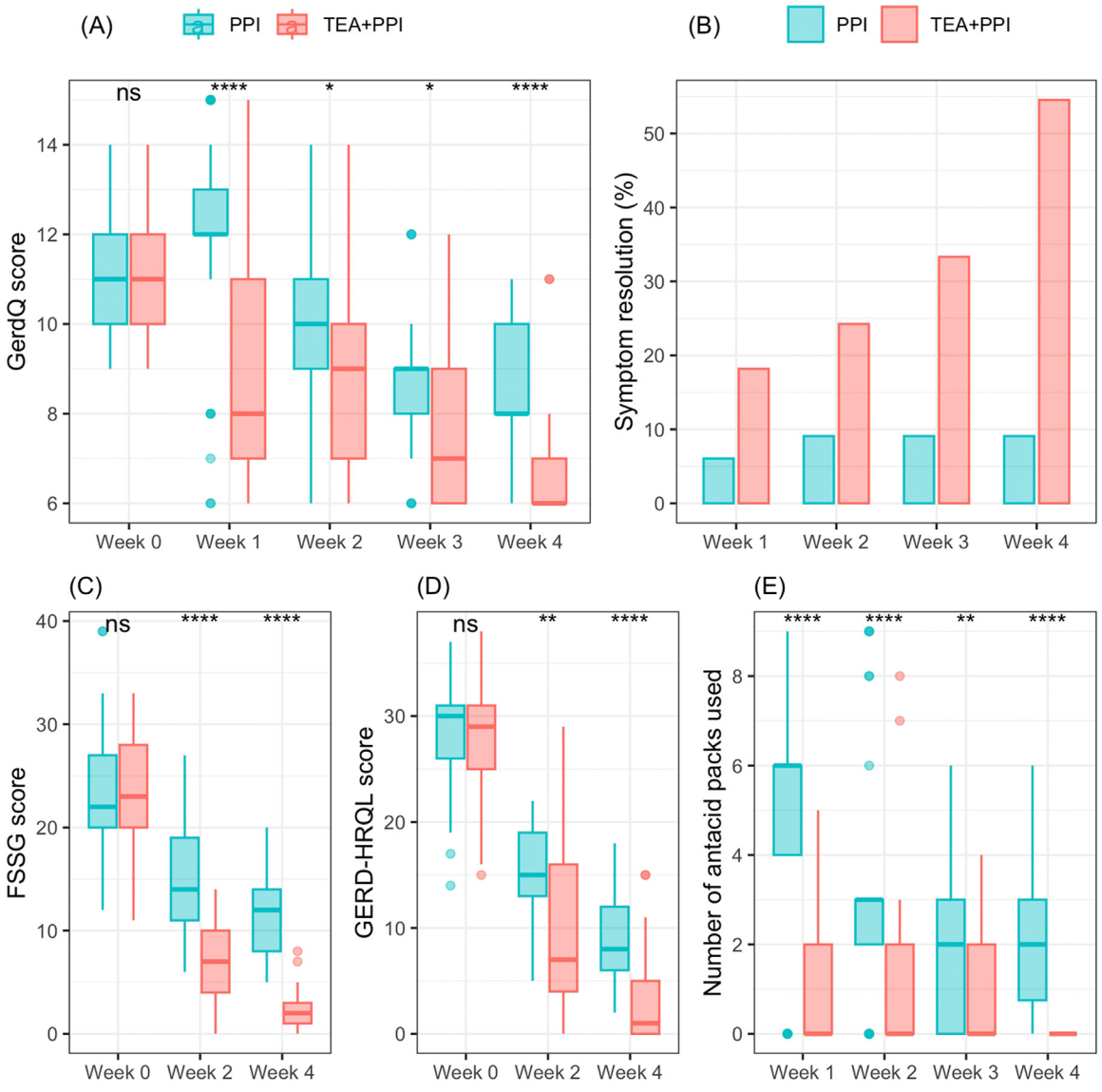

Fig. 2. Clinical outcomes between the two treatment groups.
*P < 0.05; **P < 0.01; ***P < 0.001; ****P < 0.0001; ns, not significant; FFGS, Frequency Scale for the Symptoms of GERD; GERD, gastroesophageal reflux disease; GERD-HRQL, Gastroesophageal Reflux Disease-Health Related Quality of Life; PPI, proton-pump inhibitor; TEA, thread-embedding acupuncture.

group had a significantly lower number of antacid packs used within four weeks of treatment compared with PPI (Fig. 2E, Supplement 2).

3.3.2. *Adverse events*

A total of five patients experienced any AEs. In the first TEA intervention, three patients had AEs: two (6.1%) with local hematoma and pain and one (3%) with local hematoma, pain and induration. In the second TEA intervention, four patients had AEs, including two who already had AEs at the first TEA and two new patients who had local swelling and pruritus (Supplement 3). All AEs occurred at the Neiguan (PC6) acupoint. All were mild and fully resolved within a week without any specific treatment.

4. Discussion

The results showed that the TEA+PPI group was superior to the PPI group in all outcomes. The TEA+PPI group increased the rate of typical symptom resolution, reduced the disease severity assessed by the GerdQ score and antacid use, decreased global symptoms assessed by the FSSG score, and improved the patient's quality of life. This study showed a good safety profile of TEA in patients with GERD.

Various acupuncture methods have been studied to treat GERD. A meta-analysis demonstrated that acupuncture combined with WM improved global symptoms and quality of life compared to WM alone.[8] A study by Luo *et al.* showed that TEA was highly effective in treating GERD compared to PPI treatment.[10] Our findings support the efficacy of TEA in GERD. In our study, adding TEA to standard therapy improved the efficacy in resolving symptoms and increasing the quality of life. This finding suggests that TEA could be a new combination option in treating GERD. Based on the results, we recommend that at least two TEA sessions be performed to achieve good outcomes. There needs to be evidence about whether other additional TEA sessions are beneficial.

Previous reports have shown that most of the TEA's adverse effects are local, mild, and resolved with no long-term sequelae.[21,22] Our findings are similar, demonstrating that TEA maybe a safe therapeutic approach. In our study, all AEs occurred at the Neiguan (PC6) acupoint. At this acupoint, the skin structure is thin with minimal subcutaneous tissue, mainly muscle, blood vessels, and nerves. We tried to minimize

AEs at this acupoint by using shorter needle lengths and shallower insertion depths. However, a shallower needle insertion may slow down the natural absorption of the thread, which can cause local induration. We do not recommend excluding the Neiguan (PC6) acupoint because it is the main acupoint for treating GERD. This acupoint is consistent with the theories of TM and has substantial clinical evidence.

The mechanism of TEA in the treatment of GERD had yet to be studied. TEA and acupuncture have similar principles of choosing acupoints; therefore, the mechanisms of TEA action might be similar to those of acupuncture.[9] In our study, we used acupoints based on common TM patterns, including Liver, Spleen, and Stomach disorders.[16] Ganshu (BL18), Pishu (BL20), and Zhongwan (CV12) were used according to the Shu-Mu principle to treat disorders of these organs. Zhongwan (CV12) was also combined with Zusanli (ST36) according to the principle of Mu-He to control the reverse Qi. Neiguan (PC6) is the supported acupoint for the chest area and Geshu (BL17) descends counterflow Qi. The acupoints at the intersection of the Ren vessel and Stomach and Spleen meridian are Shangwan (CV13) and Xiawan (CV10).[13,15,23] In addition, Zusanli (ST36) and Neiguan (PC6) acupoints have been shown to have a positive effect on the lower esophageal sphincter to reduce GERD.[24,25] In the study by Luo *et al.*, acupoints on the Du meridian were selected for TEA, which also showed high efficacy in treating GERD.[10] This indicates that despite different acupoint selection principles based on different TM theories, the overall efficacy of TEA is good.

The study has several limitations. First, we used diagnostic criteria for GERD based on the GerdQ scale, a subjective assessment tool. We tried to minimize this potential selection bias by many strict exclusion criteria. Second, the participants were not blinded to the treatment group. However, the accessors were blinded to minimize bias in the outcome assessment. Third, the selection of the acupoints was based on common TM patterns. It is necessary to investigate the effect of TEA based on the classification of TM patterns, thereby can individualize the treatment. Fourth, we selected multiple primary outcomes, and all were subjective. This can lead to the overestimation of the results. Finally, the follow-up period was relatively short; thus, the long-term effects of TEA are unknown.

In conclusion, the combination of TEA and PPI within four weeks shows superior effects to PPI alone in the treatment of GERD for the resolution of typical symptoms, resolving all symptoms, and improving the patient's quality of life. Further studies with longer follow-ups and focusing more on individualized TM patterns are required to confirm these findings.

CRediT authorship contribution statement

Dieu-Thuong Thi Trinh: Conceptualization, Methodology, Validation, Investigation, Data curation, Writing – review & editing, Supervision, Project administration. **An Hoa Tran:** Methodology, Validation, Formal analysis, Investigation, Data curation, Writing – original draft, Writing – review & editing, Visualization. **Minh-Man Pham Bui:** Methodology, Investigation, Writing – review & editing, Visualization. **Nguyen Lam Vuong:** Software, Formal analysis, Writing – review & editing, Visualization.

Conflicts of interest

The authors have no conflict of interests to declare.

Funding statement

None.

Ethical statement

This research was reviewed and approved by the institutional review board of the University of Medicine and Pharmacy at Ho Chi Minh City (No. 606/ HĐĐĐ-ĐHYD, dated November 16, 2021). Informed consent was obtained from all participants.

Data availability

The data that support the findings of this study are available from the corresponding authors, upon reasonable request.

Acknowledgments

The study was registered with the University of Medicine and Pharmacy at Ho Chi Minh City as a Grassroots-level research project (No. 121/2021/HĐ-ĐHYD, dated 06-Oct-2021) and was conducted at the University Medical Center Ho Chi Minh City - Branch 3. We thank the university and hospital staff who looked help in the recruitment, treatment, and follow-up of the patients in this study. We gratefully acknowledge the patients for participating in the study.

Supplementary materials

Supplementary material associated with this article can be found, in the online version, at doi:10.1016/j.imr.2023.100971.

Supplement 1. Acupoints location and device for thread-embedding acupuncture

Supplement 2. Results after four weeks of treatment

Supplement 3. Adverse events of thread-embedding acupuncture (TEA)

Supplement 4. CONSORT 2010 checklist.

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