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Short-term Results of Transcatheter Arterial Embolization for Chronic Medial Epicondylitis Refractory to Conservative Treatment: A Single-Center Retrospective Cohort Study

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Abstract

Purpose To evaluate the effectiveness and safety of transcatheter arterial embolization (TAE) for chronic medial epicondylitis (ME) refractory to conservative treatments.

Materials and Methods This retrospective study included ten patients (14 procedures) who underwent TAE between May of 2018 and April of 2020 to treat chronic ME refractory to conservative treatments for at least 3 months. Imipenem/cilastatin sodium was used in 12 procedures, and quick-soluble gelatin sponge particles were used in the ensuing two procedures as an embolic agent. The visual analogue scale (VAS, 0–10) score and Quick Disabilities of the Arm, Shoulder, and Hand (Quick-DASH) scores were assessed at baseline and at different post-treatment times (1 day; 1 week; 1, 3, and 6 months; and an open period). The clinical success of the procedure was defined as a decrease of more than 70% in the Quick-DASH scores at 6 months compared to the baseline.

Results Clinical success was achieved in 12 of 14 procedures (85.7%). No major complications were observed during the follow-up periods. The mean VAS scores were significantly decreased at 1 day, 1 week, 1 month, 3 months and 6 months (7.6 at baseline vs. 3.6, 3.6, 3.6, 3, and 0.9 after treatment; all $P < .01$). The mean Quick-DASH scores at baseline decreased significantly at 1 day, 1 week, and at 1, 3, and 6 months after treatment (71.9 vs. 48.5, 44, 37.7, 30.2, and 8.4; all $P < .01$). These improvements endured in nine patients for up to 12 months after treatment.

Conclusion TAE effectively and safely relieved pain and promoted functional recovery in chronic ME patients refractory to conservative treatments. TAE may be a feasible treatment option for patients with ME intractable to conservative treatments.

Keyword Medial epicondylitis · Embolization · Hypervascular staining · Elbow pain

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Introduction

Medial epicondylitis (ME) is a painful condition localized to the origin of the flexor–pronator tendon, and dysfunctions of these tendons are common symptoms [1, 2]. In the

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general population, the prevalence of ME is reported to be 0.4%, with the prevalence in workers as high as 4–5% [3, 4]. ME occurs due to frequent eccentric loads on the muscles responsible for biceps pronation and wrist flexion, causing microtrauma of the common flexor tendon [2]. As ME is considered to be an inflammatory disease [5], rest, physical therapy (PT), the administration of anti-inflammatory drugs, extracorporeal shock waves (ESWT), and steroid injections are used as conservative pain treatments [2, 5, 6]. However, even with multiple conservative treatments, up to 26% of ME patients suffer symptom recurrence, and over 40% live with ongoing chronic discomfort [7]. Surgery is the last treatment option, focusing on the excision of fibrotic adhesions in the affected flexor tendon area [8, 9]. However, surgery failure rates are reportedly as high as 13–17% [10, 11].

Okuno et al. was the first to report the effectiveness of a transcatheter arterial embolization (TAE) treatment in patients with various forms of tendinopathy and enthesopathy who were refractory to conservative treatments [12, 13]. A previous investigation showed a significant improvements in pain and function in cases of chronic lateral epicondylitis (LE) refractory to conservative treatments [12]. These results presented cumulative clinical success rates of 88% (21/24) and 92% (22/24) over a 6-month and a 2-year period, respectively [12].

However, it is unclear whether TAE will be effective for chronic ME refractory to conservative treatments. Therefore, the purpose of this study was to evaluate the effectiveness and safety of TAE in patients with chronic ME resistant to conservative management strategies.

Materials and Methods

Patients

This retrospective study was approved by the institutional review board (HYJ 2021-03-025) of the pertinent institution. Between May of 2018 and April of 2020, a total of 275 patients visited an elbow disease clinic at our institution. Among them, 13 patients who had chronic ME with moderate pain (10-point visual analogue scale [VAS] score $\geq$ 5) for more than 3 months despite conservative management were referred to an interventional radiology outpatient clinic.

Inclusion criteria were as follows: 1. Patients who have not responded to conservative treatments such as physical therapy, medications, or steroid injections 3 months or more after the onset of pain. 2. Patients with a depth of a partial thickness tear of the medial upper tendon less than 1/2 of the entire tendon and less than 1 cm of the width and length of the tear site according to ultrasound and MRI examinations. 3. Patients with tendinitis or tendinosis, an ill-defined hypo-echogenic swollen tendon with diffuse loss of the normal fibrillar pattern and without localized tendon rupture. The exclusion criteria were as follows: age younger than 18 years, and symptoms or signs of local infection at the pain site.

With multidisciplinary discussions with an orthopedic surgeon and interventional radiologists, ten patients (three males and seven females with a mean age of 53.9 years; range, 45–68 years) with 14 procedures were enrolled. Four patients had bilateral ME and underwent simultaneous treatments. There were no repeated TAE processes on the same lesion. The other three patients who were referred to the interventional radiology outpatient clinic received other treatments without TAE. The mean duration of symptoms was 31.3 $\pm$ 24.2 months (range, 4–86 months), and the median duration of symptoms was 26.5 months. Table 1 shows the baseline demographics and the clinical data of the enrolled subjects. Magnetic resonance imaging (MRI) (n = 7) or ultrasound (n = 3) was performed before TAE to evaluate the severity of disease and to exclude other causes of symptoms. Previous conservative treatments included the administration of nonsteroidal anti-inflammatory drugs (NSAIDs) in all procedures, PT (13 procedures), and ESWT (13 procedures).

Embolization Procedure

All TAE procedures were performed by a single interventional radiologist (S.H.L) with 6 years of experience in an outpatient setting. The corresponding author explained to patients and caregivers that TAE procedures were experimental before all TAE procedures, and written consent for the TAE procedures was obtained from all patients.

First, radiopaque markers were attached to the tender area of the medial epicondyle before the start of the procedure. Radial artery (n = 8) or common femoral artery access (n = 6) was obtained in an ultrasound-guided ipsilateral retrograde fashion under local anesthesia, followed by the insertion of a 4-Fr sheath (Terumo, Tokyo, Japan). Before catheterization, 2,000 IU of heparin (heparin sodium; Mitsubishi Tanabe Pharma Corporation, Osaka, Japan) was administered intravenously. A 4-F angiographic catheter (Judkins right catheter; Merit Medical, UT, USA) was then introduced toward the distal brachial artery. Digital subtraction angiography using an angiography suite (Artis zee PURE Biplane; Siemens, Munich, Germany) was then performed with a manual injection of 7 $-$ 10 mL of an iodinated contrast medium (Pamiray 300; Dongkook Pharmaceutical, Seoul, Korea) to identify any hypervascular staining and/or early venous drainage of the area of the medial elbow with a radiopaque marker attached. Selective arteriograms were performed using a coaxial 2.0-

Table 1 Demographic data, procedural details and clinical outcome

Patient No (%)	Sex	Age	Dominan Hand	Occupation	Manual Labor	Pain Duration (mo)	Prior Therapies	Target Arteries	Abnormal Staining	Early Venous Drainage	Embolic Agent	Embolic Volume (mL)	6-month Quick-DASH Score Decrease
1	F	51	Rt	Housewife	No	86	ESWT, NSAIDs, PT	Rt. RUA	Evident	Evident	IPM/CS (10–70um)	0.4	64.9
						62	ESWT, NSAIDs, PT	Lt. RUA	Evident	Evident	IPM/CS (10-70um)	0.4	64.5
2	F	49	Lt	Housewife	No	10	ESWT, NSAIDs, PT	Rt. RUA	NE	Evident	IPM/CS (10–70um)	1	96.4
						15	ESWT, NSAIDs, PT	Lt. IUCA	NE	Evident	IPM/CS (10-70um)	1.5	94.7
3	M	54	Rt	Cook	Yes	34	NSAIDs, PT	Rt. RUA	Evident	NE	IPM/CS (10–70um)	2.8	100
4	F	59	Rt	Housewife	No	6	ESWT, NSAIDs, PT	Lt. IUCA	NE	Evident	IPM/CS (10-70um)	2	100
5	M	45	Rt	Carpenter	Yes	19	ESWT, NSAIDs, PT	Rt. IUCA	NE	Evident	IPM/CS (10–70um)	0.7	78.4
						4	ESWT, NSAIDs, PT	Lt. IUCA	NE	Evident	IPM/CS (10–70um)	1.2	71.8
6	F	47	Lt	Housewife	No	32	ESWT, NSAIDs, PT	Lt. IUCA	Evident	Evident	IPM/CS (10–70um)	1	100
7	M	49	Rt	Production-line worker	Yes	21	ESWT, NSAIDs, PT	Rt. IUCA	Evident	Evident	IPM/CS (10–70um)	0.8	100
8	F	60	Rt	Housewife	No	54	ESWT, NSAIDs	Lt. RUA	Evident	Evident	IPM/CS (10–70um)	1.2	93.9
9	F	59	Rt	Housewife	No	10	ESWT, NSAIDs, PT	Rt. RUA	Evident	Evident	IPM/CS (10–70um)	2	96.2
10	F	68	Rt	Housewife	No	37	ESWT, NSAIDs, PT	Rt. RUA	Evident	Evident	Nexsphere® (100–300um)	5	96
						48	ESWT, NSAIDs, PT	Lt. IUCA	NE	Evident	Nexsphere® (100–300um)	1	92.9

ESWT extracorporeal shock waves, *Lt* left, *NE* not evident, *NSAIDs* nonsteroidal anti-inflammatory drugs, *PT* physical therapy, *Rt* right, *RUA* recurrent ulnar artery, *IUCA* inferior ulnar collateral artery, *IPM/CS* imipenem/cilastatin sodium, *Nexsphere®* quick-soluble gelatin sponge microsphere, *Quick-DASH* Quick Disabilities of the Arm, Shoulder, and Hand

F micro-catheter (Radiomate; S&G Biotech, Gyeonggi-do, Korea) and a micro-guidewire (Ez; S&G Biotech). The targets of the selective arteriograms included the inferior ulnar collateral artery (IUCA) and the recurrent ulnar artery (RUA). A suspension of 0.5 g imipenem/cilastatin sodium (IPM/CS, Prepenem, which is the generic drug of Primaxin® [Merck & Co. Inc., Whitehouse Station, NJ, USA]; JW Pharmaceutical, Seoul, Korea) in 7 mL of an iodinated contrast medium was used as an embolic agent in first 12 procedures [14]. However, IPM/CS is an antibiotic whose use is restricted by government policy, making its continued use difficult. Therefore, a suspension of 0.2 g of quick-soluble gelatin sponge particles (Nexsphere 100–300um [degradation time < 10 h]); Next Biomedical, Incheon, Korea) in 5 mL of iodinated contrast medium was used in the subsequent two procedures as an embolic agent. After confirming the locations of hypervascular staining and/or early venous drainage as previously described [12, 14–16], which were correlated to the pain site, an embolic agent suspension was prepared and then injected in 0.2 mL increments, after which it was flushed with an equal amount of normal saline. This was repeated until stagnation of the blood flow. Completion angiography was then performed to confirm the reduction of hypervascular staining and/or early venous drainage. If any remaining lesions were found, repeated embolization was performed using the suspension. It took approximately 20 min from the arterial puncture to the end of the procedure. The patients were then discharged on the same day after hemostasis. Successful selective embolization of at least one feeding artery to hypervascular staining and/or early venous drainage was defined as technical success.

Assessment and Follow-Up

All patients were allowed to return gradually to heavy work or sports 2 weeks after the TAE procedure. If pain persisted, patients could continue with conservative treatments. All patients completed VAS scoring for maximum pain and Quick Disabilities of the Arm, Shoulder, and Hand (Quick-DASH) questionnaires as measures of their physical function and symptoms. The time points of the evaluation consisted of baseline and 1 day, 1 week, 1 month, 3 months, and 6 after TAE and at any period after 6 months if available. Follow-up MRI was performed in two procedures at 6 months after TAE to evaluate the degree of tendinopathy changes and to check for any complications. Clinical success of the procedure was defined as a decrease of more than 70% in Quick-DASH scores at 6 months compared to the baseline score [12]. Changes in the use of conservative treatments (PT, NSAIDs, and ESWT) during the follow-up period were recorded.

Adverse events were based on the Cardiovascular and Interventional Radiological Society of Europe (CIRSE) Classification System [17]. Minor adverse events were defined as CIRSE grades 1–2 and major adverse events as CIRSE grades 3–5. Muscle weakness, tissue necrosis, and paresthesia were defined as major adverse events, whereas puncture site hematomas, puncture site pain, and skin redness were defined as minor events. All of these potential adverse events were evaluated during the same follow-up period.

Statistical Analysis

The Kolmogorov–Smirnov test was used to test the normality of the baseline and outcome variables. The Wilcoxon signed-rank test was used to compare the baseline and each of the follow-up Quick-DASH and VAS scores. A P value of < 0.05 was considered statistically significant. All statistical data analyses were performed using SPSS software (IBM SPSS Statistics for Windows, Version 20.0. Armonk, NY: IBM Corp.).

Results

Technical and Clinical Outcomes

TAE was performed successfully in all patients. There were no major adverse events related to TAE procedures. Three patients experienced radial puncture site pain after TAE, and these were resolved with analgesics. The mean Quick-DASH scores at baseline decreased significantly 1 day; 1 week; and 1, 3, and 6 months after TAE (71.9 versus 48.5, 44, 37.7, 30.2, and 8.4, respectively; all $P < 0.01$). Clinical success 6 months after the TAE procedures was achieved in 12 of 14 cases (85.7%). The mean VAS scores were significantly decreased 1 day; 1 week; and 1 month, 3 months, and 6 months (7.6 at baseline versus corresponding scores of 3.6, 3.6, 3.6, 3, and 0.9 after the treatment; all $P < 0.01$). These improvements remained in nine procedures up to 1 year of follow-up (Fig. 1). The use of NSAIDs and the frequency of PT and ESWT in patients tended to decrease during the follow-up period (Table 2).

Angiographic Findings

TAE was performed by selecting only one of the target arteries, RUA (7 procedures) or IUCA (7 procedures). Hypervascular staining was identified in six out of seven procedures treated with RUA (Fig. 2) and in two out of seven procedures treated with IUCA. Hypervascular staining was identified in eight procedures out of a total of 14 procedures. Early venous drainage was observed via angiography assessments in 13 of 14 procedures (Fig. 3). Figure 4 shows definite angiographic findings of hypervascular staining.

Discussion

In a study of patients with chronic tendinopathy, vasculoneural growth in the area of pain was reported [18, 19]. Inflammation is known to stimulate neovasculo-nerve growth around affected tendons [20, 21]. It also contributes to pain by increasing the responsiveness of peripheral nociceptive neurons and the degree of pain sensitivity [20–22]. The inflammatory process is known to be maintained by the transport of pro-inflammatory cytokines, inflammatory cells, nutrients, and oxygen through the new blood vessels in the area of the pain [19, 21–23]. The exact mechanisms of TAE for pain relief are still unclear, but two possible explanations have been suggested. First, inflammation can be reduced by embolizing these new vessels [12, 13, 22]. Second, the stimulation of unmyelinated

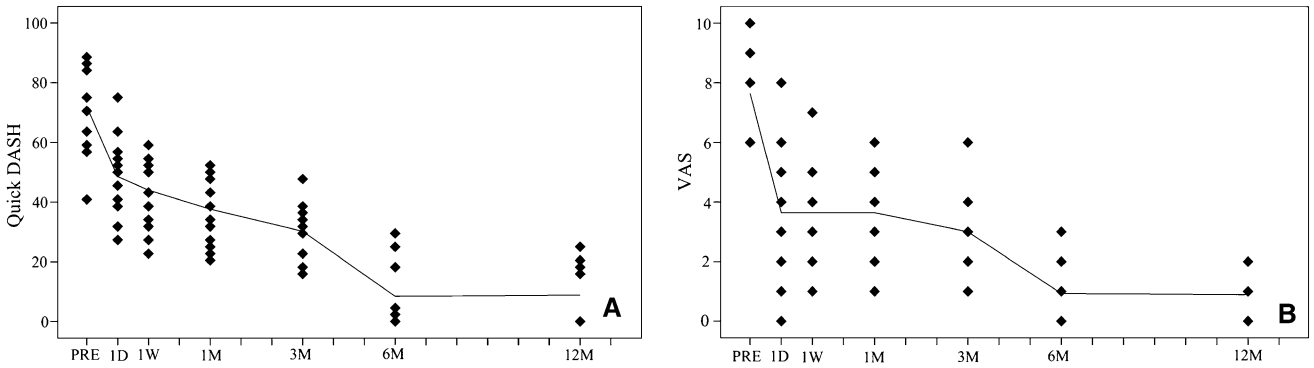

Fig. 1 Changes in mean (**A**) Quick Disabilities of the Arm, Shoulder, and Hand (Quick-DASH) score (line) and (**B**) visual analogue scale (VAS) scores (line) after transcatheter arterial embolization. Each dot represents a patient's Quick-DASH and VAS score at the relevant time after embolization

Table 2 Changes in quick-DASH scores, VAS scores and conservative treatments throughout the study

Variable	Baseline (n = 14)	1 Day (n = 14)	1 Week (n = 14)	1 Month (n = 14)	3 Months (n = 14)	6 Months (n = 14)	12 Months (n = 9)
Quick-DASH (mean ± SD)	71.9 ± 14.4	48.5 ± 12.6	44.0 ± 11.9	37.7 ± 10.9	30.2 ± 9.3	8.4 ± 10.9	8.8 ± 10.7
VAS (mean ± SD)	7.6 ± 1.2	3.6 ± 2.8	3.6 ± 1.9	3.6 ± 1.8	3 ± 1.4	0.9 ± 0.8	0.9 ± 0.8
Number of procedures receiving ESWT	13	0	0	0	0	1	2
Number of procedures receiving NSAIDs	14	2	4	2	2	0	0
Number of procedures receiving PT	13	3	3	3	3	2	2

Quick-DASH Quick Disabilities of the Arm, Shoulder, and Hand, *VAS* visual analog scale (0–10), *ESWT* extracorporeal shock waves, *NSAIDs* nonsteroidal anti-inflammatory drugs, *PT* physical therapy, *IPM/CS* imipenem/cilastatin sodium

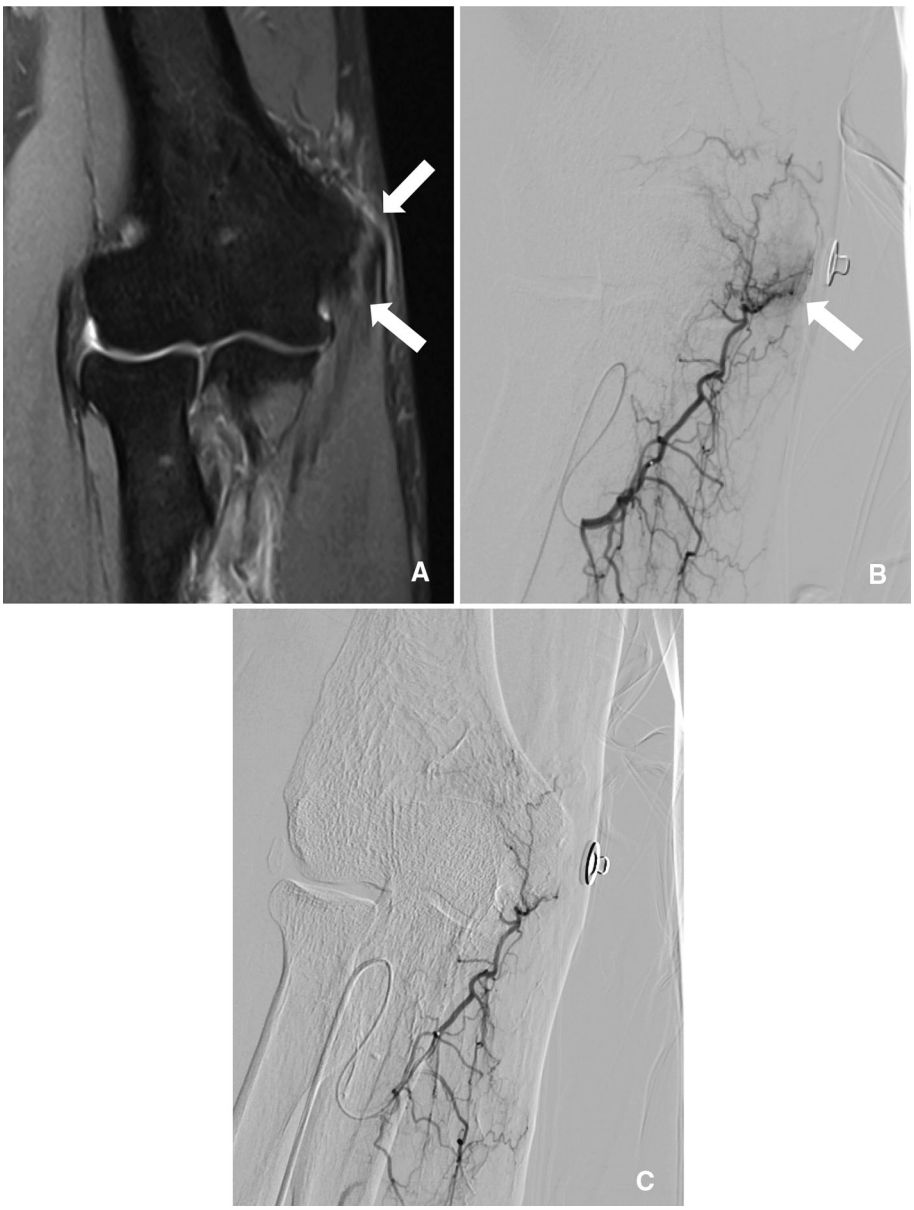

Fig. 2 MRI and before-and-after angiographic findings of transcatheter arterial embolization in a 54-year-old male with right medial epicondylitis. **A** Coronal fat-suppressed proton-density MRI showing moderate tendinosis of the proximal common flexor tendon, consistent with medial epicondylitis (white arrow). **B** Pre-embolization selective angiography from the recurrent ulnar artery showing hypervascular staining adjacent to the medial epicondyle (white arrow). **C** Post-embolization selective angiography showing the disappearance of hypervascular staining

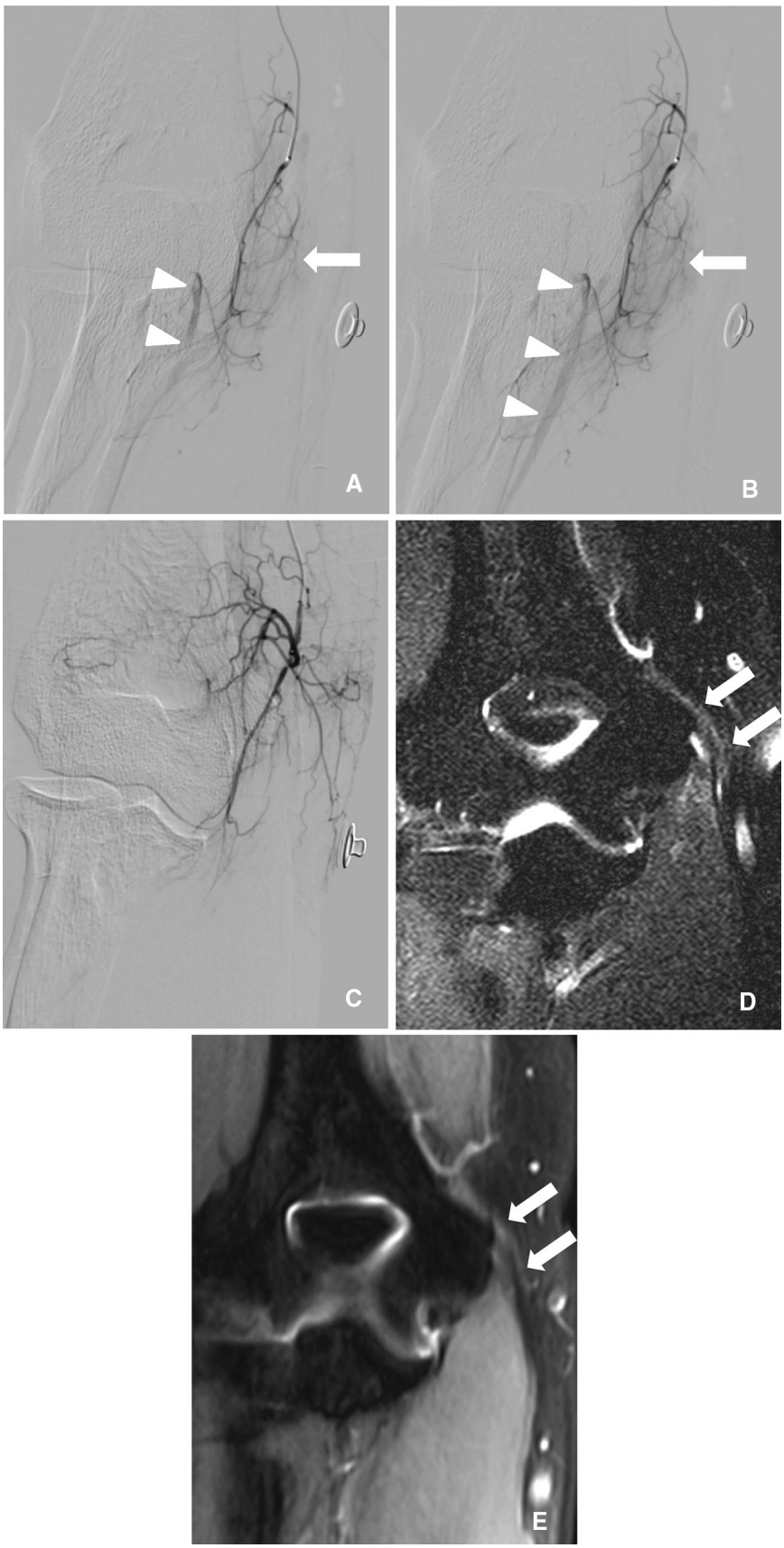

Fig. 3 Before-and-after angiographic findings and before-and-six-month follow-up MRI outcomes of transcatheter arterial embolization (TAE) in a 45-year-old male with right medial epicondylitis. **A-B** Pre-embolization selective angiography from the inferior ulnar collateral artery showing no hypervascular staining adjacent to the medial epicondyle (white arrow). Early venous drainage is observed before arterial contrast filling is achieved (white arrowheads). **C** Post-embolization selective angiography showing the disappearance of early venous drainage. **D** T2 coronal fat saturation image showing increased signals around the medial epicondyle and along the common flexor tendon fibers, consistent with medial epicondylitis (white arrow). **E** Six months after the TAE procedure, previously increased signals do not appear in a PD coronal fat saturation image

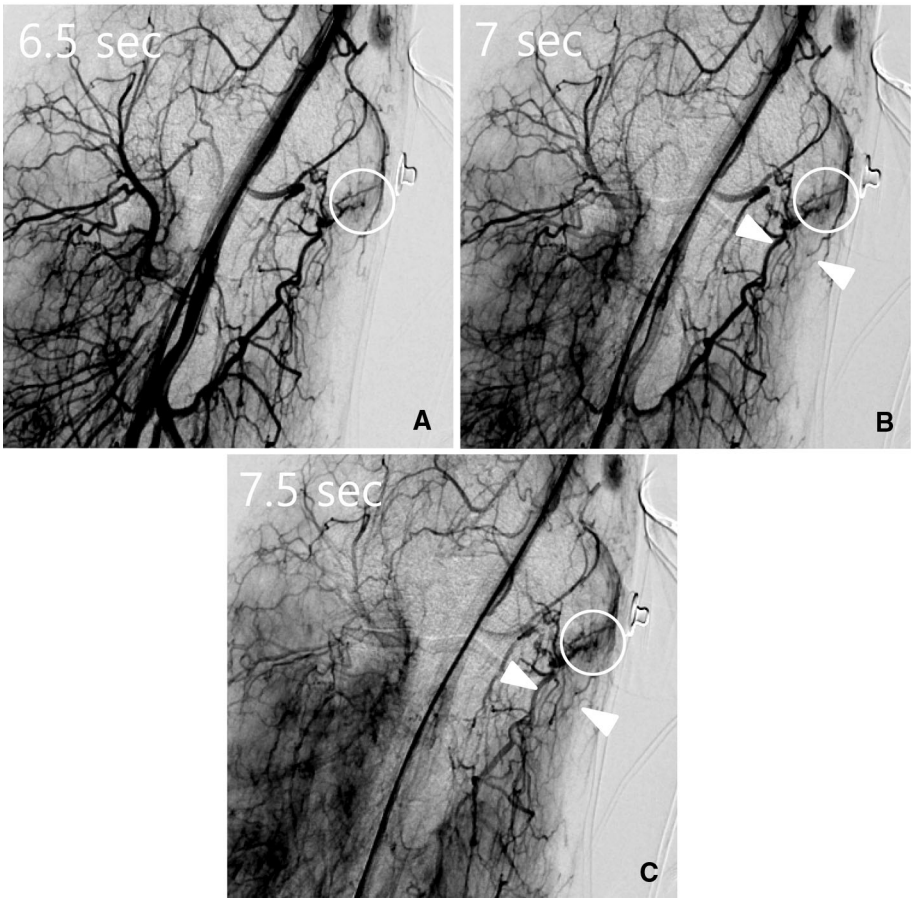

Fig. 4 Pre-embolization angiographic findings in a 54-year-old male with right medial epicondylitis in the right distal brachial artery. **A-C** Hypervascular staining around the medial epicondyle is observed from 6.5 s (**A,** white circle). Normal vessel staining around the common flexor tendon is observed from 7 s (**B,** white arrowheads). Hypervascular staining is identified in the early phase compared to normal vessel staining around the common flexor tendon

sensory nerve growth affected by inflammation may be decreased after embolization [14, 22].

According to these hypotheses, previous studies have focused on performing embolization by identifying hypervascular staining during TAE [12–16, 22–25]. However, hypervascular staining is not always observed during TAE treatments for tendinopathy [14]. A previous report regarding tendinopathy showed that hypervascular staining was observed only in ten of fifteen procedures (66.7%) [14]. Interestingly, early venous drainage was observed in five of seven patients with adhesive capsulitis and 22 of 24 patients with lateral epicondylitis [12, 16]. In this study, hypervascular staining was observed in eight of fourteen procedures, and early venous drainage was present in all except one procedure. For this reason, even if hypervascular staining was not observed, TAE was performed if early venous drainage was present, and clinical success was achieved in these procedures. It is presumed that the presence of only early venous drainage may be due to fine abnormal neovascularization too fine even to be recognized by angiography. Therefore, even when hypervascular staining is not observed during an angiographic evaluation, identifying early venous drainage may be helpful to determine whether or not to perform TAE.

In this study, quick-soluble gelatin sponge microspheres were used as a transient embolic agent in one patient (two procedures). The Quick-DASH score and VAS score were both significantly decreased, and clinical success was also achieved. No adverse events including skin color changes occurred in this patient. Previous study reported that the incidence of any transient skin color change was relatively low in an IPM/CS group compared to a group using permanent embolic particles [22]. As IPM/CS is a restricted antibiotic and its use for arterial embolization is still controversial, the use of quick-soluble gelatin sponge microspheres may be a viable alternative option during TAE treatments. However, there remain too few procedures at present, and further large-scale investigations are therefore needed.

Our study has several limitations. First, this is a single-center retrospective study which did not have a control group. Therefore, a placebo effect cannot be excluded. Second, relatively few patients with a short follow-up period were included in this study. Moreover, patients could continue with a conservative therapy during the follow-up period, which hinders an exact assessment of the effectiveness of the TAE treatment here. However, there was a decreasing tendency of any need for conservative

therapy after TAE. Owing to these limitations, we have not been able to conclude with certainty that TAE is superior compared to a conservative treatment. Third, although this was an inevitable problem due to the aforementioned restrictions on antibiotic use, it is possible that the lack of uniformity of the embolic agent (IPM/CS in twelve procedures and quick-soluble gelatin sponge particles in two procedures) affected the outcome. To overcome these limitations, a well-designed randomized controlled trial is required to assess the effects of TAE on ME more accurately.

In conclusion, TAE effectively and safely relieved pain and promoted functional recovery in chronic ME patients refractory to conservative treatments. TAE may be a feasible treatment option for patients with ME intractable to conservative treatments.

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Declarations

Conflict of interest The authors declare that they have no conflict of interest.

Ethical Approval This retrospective study was approved by the institutional review board (IRB). For this type of study formal consent is not required.

Informed Consent This study has obtained IRB approval from H Plus *Yangji* Clinical Research Center and the need for informed consent was waived.

Consent for publication For this type of study consent for publication is not required.

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