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CLINICAL INVESTIGATION ARTERIAL INTERVENTIONS

Clinical Outcomes of Transcatheter Arterial Embolisation for Chronic Knee Pain: Mild-to-Moderate Versus Severe Knee Osteoarthritis

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Abstract

Purpose This retrospective study was conducted to compare the clinical outcomes of transcatheter arterial embolisation for chronic knee pain in patients with mild-to-moderate versus severe knee osteoarthritis.

Materials and Methods This study included patients ($n = 41$) who were refractory to conservative treatments and who underwent transcatheter arterial embolisation using imipenem/cilastatin sodium between June 2017 and July 2018. A total of 71 knees, including 30 bilateral cases, were treated and categorised into two groups according to the Kellgren–Lawrence grade: mild-to-moderate osteoarthritis ($n = 59$, Kellgren–Lawrence grade 1–3) and severe osteoarthritis ($n = 12$, Kellgren–Lawrence grade 4). The clinical outcomes were measured by the visual analogue scale score.

Results There were no significant differences in age, body mass index or baseline visual analogue scale scores between the two groups. The mean visual analogue scale scores in the mild-to-moderate osteoarthritis group were significantly decreased at 1 day, 1 week, 1 month, 3 months, and 6-months (5.5 at baseline vs. 3.2, 3.1, 2.9, 2.2, and 1.9, after treatment; all $P = .00$). These improvements were maintained at a mean of 10 ± 3 months (range 6–19 months) post-treatment. The visual analogue scale scores were significantly decreased in the severe osteoarthritis group for 1 month post-treatment (6.3 at baseline vs. 4.1, 4.1, and 4.4 at 1 day, 1 week, and 1 month; all $P < .01$). However, a decrease in pain was not statistically significant from 3 to 6 months (5.4 and 5.9 at 3 months and 6 months, respectively).

Conclusion Transcatheter arterial embolisation effectively relieved pain in patients with mild-to-moderate osteoarthritis. In patients with severe osteoarthritis, pain severity decreased for 1 month but gradually increased to the initial severity score within 3 months.

Level of Evidence 4, Case series.

Keywords Abnormal neovessels · Embolisation · Osteoarthritis · Knee pain

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Introduction

Knee osteoarthritis (OA) is a common disease among the elderly [1]. The prevalence of knee OA has increased, which has been attributed to the general increases in both life expectancy and the body mass index (BMI) [2, 3].

Pain is the most significant symptom of knee OA [4]. Symptomatic severe OA can be treated by joint replacement surgery [4–6]. Additionally, arthroscopic lavage and debridement, cartilage repair techniques, and knee osteotomies are performed as surgical treatments for knee OA according to the stage [7]. Surgical treatments are considered only if multiple conservative treatment options were attempted but did not have the desired effects [8].

Okuno et al. [4, 6] showed that effective pain relief by transcatheter arterial embolisation (TAE) treatment in mild-to-moderate knee OA patients who were refractory to conservative treatments. The results showed cumulative clinical success rates of 86.3% and 79.8% over a 6-month and a 3-year period, respectively [6]. However, in these previous studies, severe knee OA patients who were refractory to conservative treatments were excluded from TAE in favour of joint replacement surgery [4, 6]. Among these patients, joint replacement surgery may be difficult in those who are not suitable for general anaesthesia or do not desire surgery. The effectiveness and safety of TAE procedures in such patients have not yet been reported. Therefore, in the current study, the TAE procedure was performed to treat chronic knee pain in mild-to-severe OA patients. The effectiveness and safety of the TAE procedure were compared between two patient groups: mild-to-moderate OA and severe OA.

Materials and Methods

This retrospective study was approved by the institutional review board, and the requirement for informed consent was waived.

Enrolled Cases

TAE procedures for 78 knees in 45 patients were performed at our institution between June 2017 and July 2018. Among them, four patients with seven TAE procedures were excluded from this study because they were unable to be available for follow-up after the procedure. Finally, a total of 71 knees in 41 patients, including 30 bilateral cases, were treated by TAE and were enrolled in this study.

The TAE procedure was performed only in knee OA patients who were refractory to conservative treatments, including physical therapy, muscle strengthening, nonsteroidal anti-inflammatory drugs (NSAIDs), and intra-articular hyaluronic acid injection therapy, and who had experienced mild-to-severe pain (10-point visual analogue scale [VAS] score ≥ 2) for more than 3 months. All patients underwent knee plain radiography, and their Kellgren–Lawrence (KL) grades [9] were determined based on knee anterior–posterior radiography. Knee magnetic resonance imaging (MRI) was performed in 12 of 45 patients.

The enrolled cases had mild (KL grade 1–2), moderate (KL grade 3), and severe (KL grade 4) OA. Patients of KL grade 4 were enrolled in this study if they were not suitable for general anaesthesia or did not want joint replacement surgery. All enrolled cases ($n = 71$) were categorised into the two groups according to the KL grade: mild-to-moderate OA ($n = 59$, KL grade 1–3) and severe OA ($n = 12$, KL grade 4) groups. Table 1 shows the baseline demographics and clinical characteristics of the enrolled cases.

Embolisation Procedure

Femoral artery access was obtained in an ultrasound-guided ipsilateral antegrade fashion under local anaesthesia followed by the insertion of a 5-Fr sheath (Terumo, Tokyo, Japan). Before catheterisation, 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 towards the distal superficial femoral artery. Digital subtraction angiography using a biplane angiography machine (Artis zee PURE Biplane; Siemens, Munich, Germany) was then performed by manually injecting 7–10 mL of iodinated contrast medium (Pamiray 300; Dongkook Pharmaceutical, Seoul, Korea) to identify the vascular anatomy and any abnormal staining. The patient was then asked to indicate which part of the knee was painful. Selective arteriograms were performed by selecting arteries in the painful areas [6], and the site was checked for abnormal staining. Selective arteriograms were performed using a coaxial 2.0-F microcatheter (Radiomate; S&G Biotech, Gyeonggi-do, Korea) and a microguidewire (Ez; S&G Biotech). The targets of the selective arteriograms included the descending genicular artery, superior patellar artery, superior and inferior medial genicular arteries, superior and inferior lateral genicular arteries, median genicular artery, and the anterior tibial recurrent artery. 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 iodinated contrast medium was used as an embolic agent. After confirming that the abnormal

Table 1 Baseline demographic and clinical characteristics of the enrolled cases

Characteristics	Mild-to-moderate OA (*n* = 59)	Severe OA (*n* = 12)	*P* value*	All enrolled cases (*n* = 71)
Age (years), mean ± SD (range)	66.2 ± 6.7 (47–80)	68.1 ± 6.5 (56–74)	0.421	67.2 ± 6.8 (47–80)
Gender (M/F)	15:44	2:10	0.718	17:54
Embolisation (right/left)	29:30	6:6	1.000	35:36
Pain duration (mo), mean ± SD	58.4 ± 67.2	134.0 ± 58.6	0.000	73.2 ± 72.2
KL grade, mean ± SD	2.5 ± 0.7	4	0.000	2.7 ± 0.9
BMI (kg/m^2), mean ± SD	24.6 ± 3.6	25.0 ± 4.1	0.339	24.9 ± 3.7
10-point VAS score, mean ± SD (range)	5.5 ± 2.2 (2–10)	6.3 ± 2.3 (2–9)	0.262	5.6 ± 2.2 (2–10)

OA osteoarthritis, *KL* Kellgren–Lawrence, *BMI* body mass index, *VAS* visual analogue scale

*Comparison between the mild-to-moderate and severe OA groups

staining was consistent with the pain site, an IPM/CS suspension was prepared by pumping a syringe 20 times. The suspension was then injected in 0.2 mL increments until the blood flow was stagnated. Haemostasis of the arterial access was achieved using a vascular closure device (FemoSeal; Terumo, Tokyo, Japan) in addition to 2 h of patient bed rest after removal of the femoral sheath. The patients were then discharged on the same day.

Assessment and Follow-Up

Clinical and radiological data of the patients were obtained from the hospital's electronic medical record system and its picture archiving and communication system. Knee pain was measured based on the VAS score while the patients were walking [4]. The changes in the VAS scores of the patients were measured at the baseline and then at 1 day, 1 week, 1 month, 3 months, 6 months, and in an open period after the TAE procedures. During the same follow-up period, any changes in the conservative treatments, including physical therapy, NSAIDs, and intra-articular hyaluronic acid injection therapy that the patients had been receiving prior to TAE were recorded. The clinical outcomes in the two groups were compared between the two groups: mild-to-moderate (KL grade 1–3) OA ($n = 59$) and severe (KL grade 4) OA ($n = 12$). The clinical success of the procedure was defined as a decrease of at least 50% in the VAS score compared to the baseline [10, 11]. Adverse events were based on the Cardiovascular and Interventional Radiological Society of Europe Classification System [12]. Minor adverse events were defined as CIRSE grade 1–2 and major adverse events as CIRSE grade 3–5. Knee instability, muscle weakness, newly developed pain, and paraesthesia were defined as major adverse events, whereas puncture site haematomas, skin redness, and transient fevers were defined as minor events. All of these potential events were assessed during the follow-up period.

Statistical Analysis

Age, BMI, and baseline VAS scores in the mild-to-moderate OA and severe OA groups were compared with the results of a rank ANCOVA test. The VAS scores at the baseline and the follow-up periods (1 day, 1 week, 1, 3, and 6 months) post the TAE procedures were compared using the Wilcoxon signed-rank test. A P value of $< .05$ was considered statistically significant. All statistical data were analysed using the SPSS software (IBM SPSS Statistics for Windows, Version 20.0. Armonk, NY: IBM Corp.).

Results

Clinical Outcomes

TAE was successfully performed in all patients. No major adverse events due to the procedure were recorded. There were 59 cases with mild-to-moderate OA and 12 cases with severe OA. There were no significant differences in age or BMI between the two groups (age, $P = 0.421$; BMI, $P = 0.339$). The baseline VAS scores were 5.5 ± 2.2 (range 2–10) and 6.3 ± 2.2 (range 2–9) in the mild-to-moderate and severe OA groups, respectively, ($P = .262$).

In the mild-to-moderate OA group, the mean VAS scores decreased significantly during the follow-up period from the baseline to 6 months after the TAE procedure (all $P = .00$) (Fig. 1). The mean VAS scores at the baseline and 1 day, 1 week, 1 month, 3 months, and 6 months after the TAE procedure were 5.5 ± 2.2 and 3.2 ± 2.1, 3.1 ± 1.8, 2.9 ± 1.7, 2.2 ± 1.7, and 1.9 ± 1.5, respectively, (all $P = .00$). Clinical success was achieved 3 months after the procedures were performed, which was well maintained at the final follow-up examination with a mean of 10 ± 3 months (range 6–19 months) after the TAE procedure.

Fig. 1 Plain radiography, MRI, and before-and-after angiographic findings of the transcatheter arterial embolisation (TAE) in a 65-year-old male with Kellgren–Lawrence (KL) grade 3 osteoarthritis (OA). The patient's pain was in the medial area of the right knee. **A** Standing anterior–posterior radiography of the right knee showing KL grade 3 in the medial tibiofemoral joint OA. **B** Coronal fat-suppressed proton density MRI showing a degenerative tear in the medial meniscus (white arrow) and a partial tear in the medial collateral ligament with abnormal hyperintensity (white arrowheads). **C** Pre-embolisation selective angiography from the descending genicular artery (white arrow) showing abnormal staining adjacent to the medial femoral condyle (white arrowheads). **D** Post-embolisation selective angiography showing the disappearance of abnormal staining

In the severe OA group, the mean VAS scores at the baseline and 1 day, 1 week, 1 month, 3 months, and 6 months after the TAE were 6.3 ± 2.2 and 4.1 ± 2.1, 4.1 ± 2.1, 4.4 ± 2.0, 5.4 ± 1.9, and 5.9 ± 2.0, respectively. In these patients, the mean VAS scores were statistically significantly decreased for the first month after the TAE ($P < .01$); however, the mean VAS scores deteriorated again after 1 month and clinical success was not finally achieved. After 3 months, the mean VAS score tended to increase gradually towards the initial mean score. Three patients with severe OA received joint replacement surgery at the 6-month follow-up.

The use of NSAIDs and the frequency of hyaluronic acid injections and physical therapy in patients with mild-to-moderate knee OA showed a tendency to decrease during the follow-up periods. The frequency also decreased in patients with severe OA after the TAE procedure, but it showed a tendency to increase after 1 month (Table 2).

Angiographic Findings

In both groups, abnormal hypervascular staining, which was correlated with the pain site, was identified in all patients around the periarticular tissues of the knee joint, such as the synovium, fat pad, periosteum, and joint capsule. Abnormal hypervascular staining around the subchondral bone and osteochondral junction was not observed in the mild-to-moderate OA group; however, it was equivocally identified in the severe OA group.

Adverse Events

Subcutaneous haematomas at the puncture sites occurred in five patients (mild-to-moderate OA, $n = 4$; severe OA, $n = 1$), all of which were spontaneously resolved within 3 weeks. Four patients (mild-to-moderate OA, $n = 3$; severe OA, $n = 1$) experienced skin redness in the embolised area, which disappeared within 3 weeks. One patient (mild-to-moderate OA, $n = 1$) had a mild fever, which subsided within 1 day.

Table 2 Changes in visual analogue scale scores and conservative treatments throughout the study

Group	Baseline	1 Day	1 Week	1 Month	3 Months	6 Months	12 Months
Mild-to-moderate OA group (number of follow-up cases)	(n = 59)	(n = 59)	(n = 59)	(n = 59)	(n = 59)	(n = 59)	(n = 19)
VAS, mean ± SD	5.5 ± 2.2	3.2 ± 2.1	3.1 ± 1.9	2.9 ± 1.7	2.2 ± 1.7	1.9 ± 1.5	1.8 ± 2.1
Patients receiving NSAIDs	46	18	15	16	16	15	9
Patients receiving HA inj	39	0	0	2	1	1	2
Patients receiving PT	39	1	3	3	3	4	2
Severe OA group (number of follow-up cases)	(n = 12)	(n = 12)	(n = 12)	(n = 12)	(n = 12)	(n = 9)	(n = 3)
VAS, mean ± SD	6.3 ± 2.2	4.1 ± 2.1	4.1 ± 2.1	4.4 ± 2.1	5.4 ± 2.0	5.9 ± 2.1	5.3 ± 1.1
Patients receiving NSAIDs	10	2	4	4	6	5	3
Patients receiving HA inj	10	0	0	2	2	0	1
Patients receiving PT	10	0	0	1	1	0	1

KL Kellgren–Lawrence, *VAS* visual analogue scale, *NSAIDs* nonsteroidal anti-inflammatory drugs, *HA inj* intra-articular hyaluronic acid injection, *PT* physical therapy

Discussion

The mechanism of TAE as a treatment for chronic knee OA pain is as follows: Inflammation stimulates angiogenesis and unmyelinated sensory nerve growth in the periarticular tissues of the knee joint, such as the synovium, fat pad, periosteum, and joint capsule [4, 6, 13–17]. The inflammation may also increase the responsiveness of peripheral nociceptive neurons and heighten pain sensitivity, thereby contributing to an increase in the patient's sensation of pain [13, 17]. Furthermore, during inflammation, the inflammatory process is maintained by the transport of inflammatory cells, proinflammatory cytokines, nutrients, and oxygen through new vessels [4, 13, 18]. In such cases, TAE decreases the inflammatory processes associated with pain by reducing the influx of inflammatory cells and proinflammatory cytokines into the new vessels [10, 11]. In addition, as the inflammatory process is decreased by embolisation, the stimulation of unmyelinated sensory nerve growth near the new vessels may also be reduced [10, 11, 16].

The mean VAS scores of 59 knees in 33 mild-to-moderate knee OA patients decreased significantly during the 6-month follow-up period after the TAE procedures. Furthermore, clinical success was maintained at a mean of 10 ± 3 months (range 6–19 months) post-treatment. In a TAE study by Okuno et al. [6], the mean VAS scores decreased significantly from the baseline to 24 months after the procedure for 95 knees in 72 mild-to-moderate OA patients. They reported cumulative clinical success rates of 86.3% and 79.8% over 6-month and 3-year periods, respectively [6]. Overall, these results suggest that TAE is a potentially effective treatment option in mild-to-moderate OA patients who are refractory to conservative treatments.

The symptomatic severe OA patients who underwent the TAE procedure experienced decreased pain levels, but they still had pain, probably caused by subchondral bone rubbing during walking. The cause of this may be that the loss of articular cartilage in severe OA causes direct bone-to-bone contact, which can result in pain of the affected joint [19, 20]. In OA, pain in the cartilage and subchondral bone is associated with osteochondral junction angiogenesis, subchondral bone marrow lesions (characterised by angiogenesis), and subchondral bone pain fibres [21–23]. Among these causes of pain, the new vessels of the osteochondral junction and subchondral bone marrow lesions originate in the subchondral bone [22, 23]. In the subchondral bone, the arterial supply comes from the extraosseous and intraosseous compartments [24]. However, regarding the angiographic findings on TAE in the severe OA cases (n = 12), abnormal staining of the periarticular region was evident, whereas abnormal staining of the subchondral bone was equivocal (Fig. 2). For this reason, it is presumed that TAE has limited efficacy in relieving knee pain in patients with severe OA.

The two embolic materials (IPM/CS as a transient embolic particle and microsphere as a permanent embolic particle) were used in previous studies of TAE for chronic joint pain [4, 6, 10]. Previous studies reported the safety of IPM/CS as an intra-arterial embolic agent with regard to the embolisation of intestinal neoplasm bleeding in a swine model and the embolisation of abnormal new vessels in human joints [4, 6, 10, 11, 25–29]. Okuno et al. [6] reported that there was no difference in clinical outcomes between IPM/CS (n = 88) and microsphere (n = 7). Microspheres can be used in patients who are hypersensitive to IPM/CS or who are taking valproic acid [6].

Previous TAE studies using IPM/CS as an embolic agent did not report any major adverse events associated

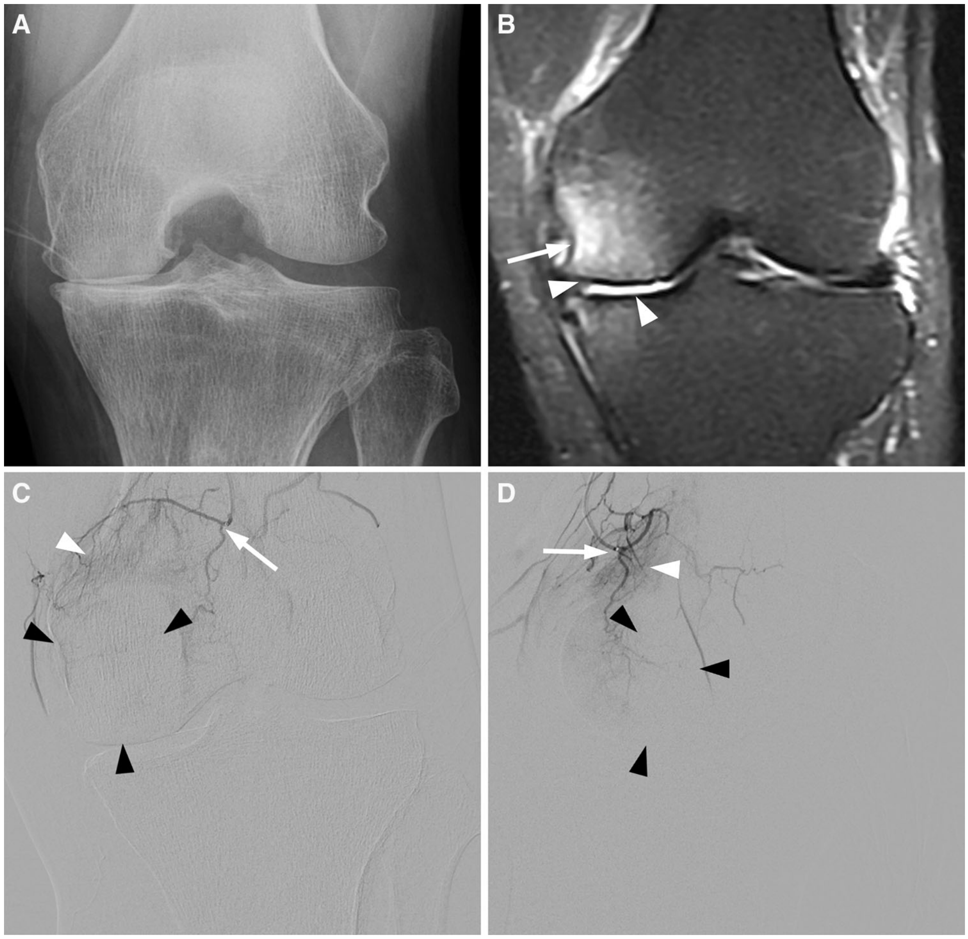

Fig. 2 Plain radiography, magnetic resonance imaging (MRI), and pre-embolisation angiographic findings of the transcatheter arterial embolisation (TAE) in a 61-year-old male with Kellgren–Lawrence (KL) grade 4 osteoarthritis (OA). The patient's pain was in the medial area of the left knee. **A** Standing anterior–posterior radiography of the left knee showing KL grade 4 medial tibiofemoral joint OA. **B** Coronal fat-suppressed STIR MRI showing subchondral bone marrow oedema in the medial femoral condyle (white arrow) and cartilage denudation (white arrowheads). Selective angiography was performed on the descending genicular artery, superior medial genicular artery, and inferior medial genicular artery to detect abnormal staining of the pain site. AP (**C**) and lateral (**D**) pre-embolisation selective angiography results from the superior medial genicular artery (white arrow) show evident abnormal staining of the periarticular region of the medial femoral condyle (white arrowhead) but equivocal abnormal staining of the subchondral bone of the medial femoral condyle (black arrowheads)

with it [4, 6, 10, 11, 25–28]. Although there have been no major adverse events, a few reports suggested the possibility of transient skin colour changes after TAE using microspheres [6, 10]. Okuno et al. [6] reported transient skin colour changes in four (57.1%) of the seven knee OA patients after TAE using microsphere. Hwang et al. [10] reported erythematous changes in the skin of the forearm in one (25.0%) of four patients with shoulder and elbow disorders (lateral epicondylitis) after TAE using microsphere. However, these changes were resolved within 1 month. In the current study, IPM/CS was used as an embolic agent, and major adverse events did not occur. Minor adverse events associated with the embolic agent were skin redness in the embolised area, which occurred in four cases (5.6%) but which disappeared within 3 weeks. A relatively low rate of transient skin colour changes appears to be an advantage of IPM/CS. However, further study is needed to evaluate the safety of IPM/CS as an embolic material for the treatment of OA.

The present study has the following limitations. First, no control group was included in this retrospective study. Second, the patient sample was small and the follow-up period was short. Third, after the TAE procedures, the patients continued the conservative therapies used before embolisation if their pain persisted, which may have biased the clinical outcomes.

In conclusion, TAE in symptomatic knee OA may be a feasible and safe treatment option. In the current study, TAE effectively relieved pain in patients with mild-to-moderate OA. However, in patients with severe OA, pain severity decreased for 1 month, but gradually increased to the initial severity score within 3 months.

Compliance with Ethical Standards

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

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

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.

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