CLINICAL INVESTIGATION



Lipiodol Versus Imipenem/Cilastatin in Genicular Artery Embolization: A Retrospective Study on Safety and Clinical Success

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Abstract

Purpose This study aims to evaluate the safety and effectiveness of genicular artery embolization (GAE) using lipiodol in comparison to imipenem/cilastatin (IPM-CS).

Materials and Methods This retrospective study screened patients who underwent GAE between January 2022 and February 2023 for inclusion. Clinical outcomes were assessed at 1, 3, and 6 months post-procedure using the Visual Analog Scale (VAS) for pain and the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) for pain, stiffness, functional capacity, and total scores. Technical and clinical success rates, complications, and patient-reported outcomes were assessed.

Results A total of 42 patients were included in the study, with 13 patients treated with lipiodol and 29 with IPM-CS for GAE. Transient skin discoloration was noted in 23.1%

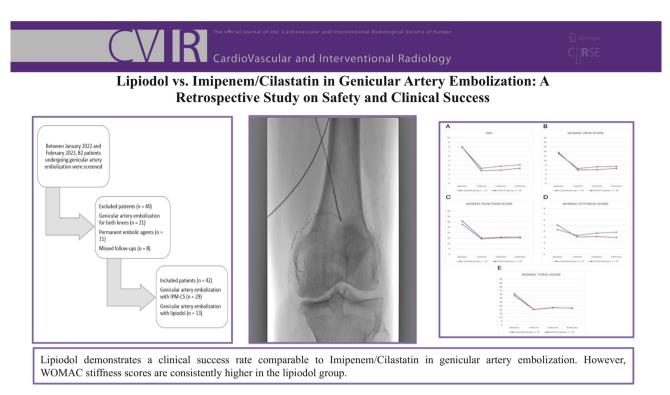
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² Department of Rheumatology, Basaksehir Cam and Sakura City Hospital, Istanbul 34480, Turkey of lipiodol patients and 31% of the IPM-CS group (p = 0.722). One patient (7.6%) in the lipiodol group developed knee edema and erythema due to drug-induced vasculitis (p = 0.309). Clinical success rates in the lipiodol group were 76.9% at 1 month, consistent at 3 months, and 69.2% at 6 months. For the IPM-CS group, success rates were 89.7, 86.2, and 75.9%, respectively, with no significant differences (p = 0.353, p = 0.657, p = 0.713). The median percentage change in WOMAC stiffness scores for the lipiodol group at 1, 3, and 6 months post-GAE were -25%, -16.7%, and -16.7%, respectively, while the IPM-CS group showed decreases of -40%, -50%, and -50%. Significant differences were found between the groups at all time points (p = 0.017, p = 0.009, and p = 0.002, respectively).

Conclusion Lipiodol shows comparable clinical success to IPM-CS in GAE.

Graphical Abstract



Keywords Genicular artery embolization · Knee osteoarthritis · Lipiodol · Transient embolic agent

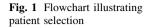
Abbreviations

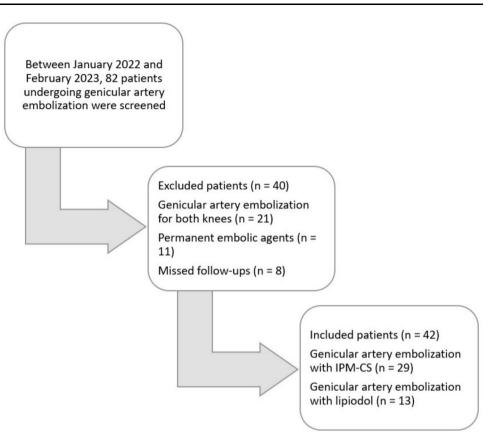
OA	Osteoarthritis				
GAE	Genicular artery embolization				
IPM-CS	Imipenem/cilastatin				
VAS	Visual analog scale				
WOMAC	Western ontario and mcmaster universities				
	osteoarthritis index				
KL	Kellgren-lawrence				
HCC	Hepatocellular carcinoma				
IQR	Interquartile range				
CRP	C-reactive protein				
INR	International normalized ratio				
eGFR	Estimated glomerular filtration rate				
SPSS	Statistical package for the social sciences				

Introduction

Recent insights into the pivotal role of angiogenesis in the pathophysiology of knee OA have brought GAE into the spotlight as an innovative treatment modality targeting angiogenesis [1–4].

Initially, Okuno et al. demonstrated favorable outcomes in reducing pain in patients undergoing GAE with imipenem/cilastatin (IPM-CS). Subsequent research has validated the safety and efficacy of GAE using various embolic agents, including both temporary and permanent microparticles [5-8]. The use of permanent microparticles, however, has raised concerns regarding non-target embolization effects. Consequently, the repercussions of extended non-target embolization with microspheres could differ from those associated with the use of imipenem/cilastatin (IPM-CS). Yet, the temporary embolic agent IPM-CS is not universally available for this indication and cannot be used in individuals with hypersensitivity to the antibiotic, thus restricting its use. For these reasons, we considered using lipiodol, a readily accessible temporary embolic agent. Its safety and efficacy for human use are well documented, and it has previously been employed as an embolic agent [6, 9].





This study aimed to retrospectively evaluate the outcomes and safety of GAE procedures using lipiodol compared to IPM-CS.

Materials and Methods

Study Design

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

Patients

Between January 2022 and February 2023, patients who underwent GAE treated with either lipiodol or IPM-CS were screened for this study. Patients who received embolization agents other than IPM-CS during the procedure (permanent embolic agents), those who underwent bilateral knee procedures, or those who did not attend follow-up appointments were excluded from the study (Fig. 1). The GAE procedure was performed on patients over the age of 40 who, despite receiving conservative treatments for OA, and having a Kellgren-Lawrence (KL) grade of \geq 2, reported a pain score of more than 4 on a 10-point visual analog scale (VAS) for over three months. Patients with rheumatological knee diseases, infectious arthritis, those who had knee arthroscopic surgery within the last six months, renal insufficiency (eGFR < 45), or coagulation disorders (INR > 1.5, platelet count < 50,000) were not eligible for the procedure. Imaging Assessment of Knee Osteoarthritis.

All participants received routine diagnostic imaging, which included plain radiography and MRI scans without contrast, before undergoing the embolization procedure. The presence of osteoarthritis was verified through knee x-rays, and the KL grading system was employed to determine the severity of the condition [10].

GAE Procedure

Each intervention was conducted by a board-certified interventional radiologist with 15 years of experience. The arterial entry site was anesthetized locally, followed by the anterograde insertion of a 5-French sheath from Cordis Medical (Florida, USA) into the common femoral artery, guided by ultrasound for precise placement. Digital subtraction angiography from the distal superficial femoral artery was utilized to delineate the genicular arteries. These arteries were then selectively catheterized using a 5-French Berenstein catheter from Cordis Medical (Florida, USA).



Fig. 2 Genicular artery embolization angiography of the left knee in a 63-year-old man with Kellgren and Lawrence grade 3 knee osteoarthritis. Embolization with lipiodol of the superior medial genicular artery (white arrow)

In instances where a hyperemic blush was detected, a 2.0 French microcatheter from Terumo (Progreat, Tokyo, Japan) was used to catheterize all branches where this blush was detected.

For the group treated with lipiodol (Lipiodol Ultra-Fluide, Guerbet), this agent was introduced into the arteries in a controlled manner, manifesting as multiple, slowmoving, radiopaque droplets (Fig. 2). For the comparison group, an embolizing solution comprising 500 mg of IPM/ CS mixed with 10 mL of iodinated contrast medium was utilized.

Embolization in both cohorts was continued until the hyperemic blush was no longer discernible, while ensuring preservation of normal arterial flow. To confirm the absence of unintended embolic dispersion, a final angiogram of the foot was executed at the conclusion of the embolization process. Following the procedure, patients were monitored and subsequently discharged four hours after confirming hemostasis via manual compression.

Assessment and Follow-up

Patient clinical and radiological data were gathered using the hospital's electronic health records and imaging systems. Follow-up evaluations were conducted at 1, 3, and 6 months post-procedure, using the VAS for pain measurement and the WOMAC index for pain, stiffness, and functional capacity [11]. Pain was rated on a VAS from 0 (no pain) to 10 (extreme pain). Adverse events were recorded at each follow-up. Major adverse events included knee instability, muscle weakness, emergent pain, or paraesthesia, while minor events included site hematoma, skin discoloration, and fever. Severity grading followed the criteria established by the Society for Interventional Radiology [12].

The primary outcome was the enumeration and characterization of adverse events associated with GAE during the follow-up period. Secondary outcomes included technical success, clinical success, and changes in VAS-WOMAC scores at designated intervals. Technical success was defined as successful selective catheterization and embolization of at least one target genicular artery. Clinical success was defined as a reduction of 50% or more in VAS pain scores from baseline, with no increase in the baseline frequency of nonsteroidal anti-inflammatory drug use or joint injections [7, 13, 14].

Statistical Analysis

Data processing and analysis were conducted using SPSS Statistics Version 25.0 (SPSS, Chicago, IL, USA). Normality of numerical variables was assessed quantitatively with the Kolmogorov-Smirnov test and graphically via Q-Q plots. Descriptive statistics were reported as medians with interquartile ranges (IQRs). Due to non-normal distribution, non-parametric tests were used. The Wilcoxon signed-rank test compared baseline VAS and WOMAC scores to those at 1, 3, and 6 months. Differences in outcomes between baseline and follow-up were analyzed using the Mann-Whitney U or Kruskal-Wallis tests. Clinical success and complication rates were analyzed using Fisher's exact test, while associations between KL grade and sex were examined with the Chi-square test. All statistical tests were set with a significance threshold of p < 0.05.

Results

Patient Demographics and Characteristics

After screening 82 patients who underwent GAE, a total of 42 participants were included in the study. Thirteen patients who had a history of hypersensitivity to antibiotics received lipiodol as the embolizing agent, and twenty-nine patients were treated with IPM-CS. The participants had a median age of 65 years (IQR, 58–70.25 years), and the cohort included 19 males and 23 females. Statistical analysis revealed no significant differences between the groups in terms of gender distribution (p = 0.936), age (p = 0.471), or body mass index (BMI) (p = 0.310). The

	Lipiodol group $n = 13$	IPM-CS group $n = 29$	P value	All enrolled cases $n = 42$	
Age (years) median (IQR)	60 (48–66.5)	67 (58.5–72.5)	0.471	65 (58–70.25)	
Gender (male / female)	6/7	13/16	0.936	19/23	
BMI median (IQR)	30 (28.4–35.3)	31.62 (29.7–33.8)	0.310	31.5(29.3-34.1)	
Kellgren-Lawrence grade 2/3/4	8/3/2	12/13/4	0.387	20/16/6	
Baseline					
VAS median (IQR)	8 (8-8)	8 (7.5–8)	0.863	8 (8-8)	
WOMAC pain median (IQR)	14 (8.5–16.5)	14 (8.5–18)	0.733	14 (8.75–17)	
WOMAC stiffness median (IQR)	4 (3.5–6)	6 (4–6)	0.245	5 (3-6)	
WOMAC function median (IQR)	47 (40–53)	49 (35.5–62.5)	0.270	48 (36.8–59.3)	
WOMAC total median (IQR)	65 (53.5–74.5)	59 (47-86)	0.796	63 (47-82.3)	

Table 1 The demographic data of the patients

IPM-CS: Imipenem/cilastatin, IQR: Interquartile Range, BMI: body mass index, VAS: Visual analog scale, WOMAC: Western Ontario and McMaster Universities Osteoarthritis Index

demographic data and clinical characteristics of the patients are summarized in Table 1.

Initial median VAS pain scores did not differ significantly between the lipiodol group and the IPM-CS group (p = 0.55). Similarly, median WOMAC scores for pain, stiffness, function, and total score showed no significant differences between the lipiodol and IPM-CS groups (p = 0.962, p = 0.504, p = 0.644, and p = 0.796, respectively).

Angiographic Findings

The technical success rate was uniform across the cohorts, with a 100% success rate observed. There was no

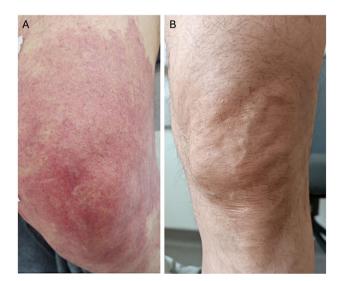


Fig. 3 A. On the 3rd day of genicular artery embolization procedure of the knee joint with lipiodol, clinical photographs showed knee edema, erythema, and non-blanching petechial rash. The skin biopsy confirmed drug (lipiodol) induced vasculitis as a moderate adverse event. **B**. The appearance of the knee after three weeks exhibiting complete resolution of skin findings with topical corticosteroids. Photographs were used with the permission of the patient

statistically significant difference in the median number of arteries embolized—four (IQR 3–4) in the lipiodol group and three (IQR 3–3) in the IPM-CS group (p = 0.060). No instances of procedural pain were reported, and subsequent control angiograms displayed no distal arterial occlusions.

Adverse Events

Small hematomas at the insertion site were noted in 15.4% (2 patients) of the lipiodol group and 10.3% (3 patients) of the IPM-CS group (mild adverse events) (p = 0.637). Stability of these hematomas was confirmed by ultrasound, and they resolved without intervention within two weeks, allowing for same-day discharge of the patients. Transient skin discoloration occurred in 23.1% (3 patients) of the lipiodol-treated patients and in 31% (9 patients) of the IPM-CS group, which resolved entirely within the first four days (mild adverse events) (p = 0.722). One patient from lipiodol group developed acute onset knee edema, erythema, non-blanching petechial rash, and elevated serum C-reactive protein (CRP) level as 48 mg/dl. The skin biopsy was performed and showed swollen endothelia, neutrophilic infiltration in vessel wall, perivascular lymphocytic, histiocytic, and neutrophilic infiltration, and extravasated erythrocytes confirming the localized druginduced vasculitis induced by lipiodol. Considering the absence of systemic vasculitis findings, only topical corticosteroids was given and at the third week after the procedure, both the rash resolved and CRP decreased to 5 mg/ dl (p = 0.309) (Fig. 3).

Clinical Outcome

Efficacy outcomes are presented in Table 2. At 1, 3, and 6 months post-procedure, the median VAS scores for the lipiodol group were 3 (IQR 2–4.5), 4 (IQR 3–4.5), and 4

	Lipiodol group $n = 13$		IPM-CS group $n = 29$		Percent change P
	Median (IQR)	Percent change from baseline, median (IQR)	Median (IQR)	Percent change from baseline, median (IQR)	value
VAS					
Month 1	3 (2-4.5)	-57 (43.8-75)	3 (2–3.5)	-62.5 (56.4-75)	0.346
Month 3	4 (3-4.5)	-50 (43.8-62.5)	3 (2-4)	-62.5 (50-75)	0.103
Month 6	4 (3–5)	-50 (37.5-62.5)	3 (2-4)	-62.5 (46.4-71.4)	0.136
WOMAC pair	n				
Month 1	7 (4-8)	-50 (43.8-61.5)	5 (3.5-8)	-55 (48.7-66.7)	0.268
Month 3	8 (5–9)	-46.7 (34.5-53.9)	6 (3.5–8)	-53.3 (47.5-68)	0.095
Month 6	8 (4.5–10)	-46.7 (31-53.9)	7 (3.5–9)	-50 (42.5-64.6)	0.109
WOMAC stiffness					
	3 (2.5–4)	-25 (0-33.3)	3 (2-4)	-40 (25-50)	0.017
	4 (3-4.5)	-16.7 (-29.2-29.2)	3 (2-4)	-50 (15.5-64.6)	0.009
	4 (3–5)	-16.7 (-29.2-25)	2 (1.5–4)	-50 (20.9-66.7)	0.002
WOMAC function					
	22 (18-28.5)	-53.2 (37.5-58.7)	21 (15-30.5)	-51.5 (42.3-60.2)	0.707
	23 (19.5-30)	-51 (30.1-58.9)	24 (16-33)	-50 (40.8-57)	0.851
	23 (20-30)	-51 (30.1-58.3)	24 (16-33.5)	-48 (40.4-57)	0.979
WOMAC total					
Month 1	34 (26.5–39)	-50 (38.2-54.2)	29 (21-42)	-52.8 (38.1-58.2)	0.501
Month 3	36 (29-44)	-43.2 (31.2-53.5)	32 (23-56.5)	-47.1 (34-56)	0.468
Month 6	37 (29.5–41.5)	-43.1 (32.2-53)	30 (23-46)	-47.1 (36.1-54.6)	0.374

Table 2 Pain and functional assessment post-genicular artery embolization

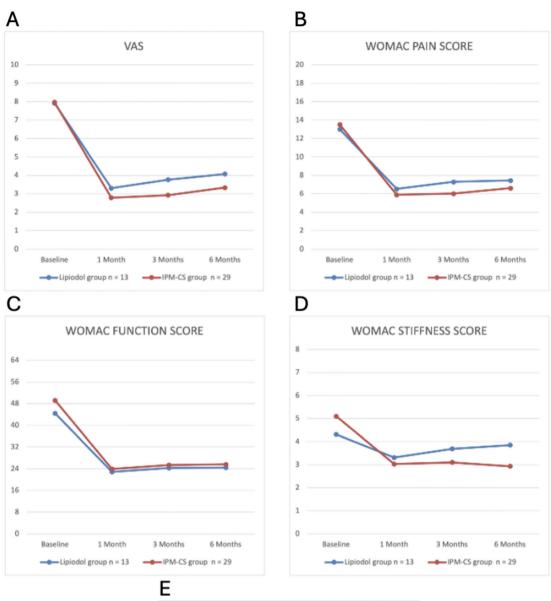
The values are given as the median, with the interquartile range (IQR) in parentheses. IPM-CS: Imipenem/cilastatin, VAS: Visual analog scale, WOMAC: Western Ontario and McMaster Universities Osteoarthritis Index

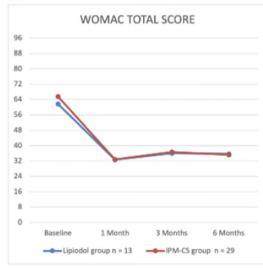
(IQR 3–5), respectively, while the IPM-CS group had scores of 3 (IQR 2–3.5), 3 (IQR 2–4), and 3 (IQR 2–4). The median percentage change in VAS scores at these intervals for the lipiodol group was -57, -50, and -50%, compared to -62.5, -62.5, and -62.5% in the IPM-CS group, with no significant differences between the groups (p > 0.05). Success rates in the lipiodol group were 76.9% at 1 and 3 months, and 69.2% at 6 months, while in the IPM-CS group, rates were 89.7%, 86.2%, and 75.9%, respectively, also showing no significant differences (p > 0.05).

At 1, 3, and 6 months post-procedure, the median WOMAC pain scores for the lipiodol group were 7 (IQR 4–8), 8 (IQR 5–9) and 8 (IQR 4.5–10), respectively. For the IPM-CS group, the scores were 5 (IQR 3.5–8), 6 (IQR 3.5–8) and 7 (IQR 3.5–9). The median percentage changes in WOMAC pain scores for the lipiodol group were – 50, – 46.7, and – 46.7%, while the IPM-CS group had changes of – 55, – 53.3, and – 50%. There were no

significant differences between the groups at any interval (p = 0.346, p = 0.095, p = 0.109, respectively).

The median WOMAC total scores for the lipiodol group were 34 (IQR 26.5-39), 36 (IQR 29-44) and 37 (IQR 29.5-41.5) at 1, 3, and 6 months post-procedure. For the IPM-CS group, the scores were 29 (IQR 21-42), 32 (IQR 23-56.5) and 30 (IQR 23-46) respectively. The percentage changes in WOMAC total scores for the lipiodol group at these intervals were -50, -43.2, and -43.1%, while the IPM-CS group showed changes of -52.8, -47.1, and -47.1%. There were no significant differences between the groups at any of the time points (p = 0.501, p = 0.468, p = 0.374). The median percentage change in WOMAC stiffness scores at 1 month, 3 months, and 6 months post-GAE for the lipiodol group showed reductions of -25, - 16.7, and - 16.7%, respectively. In contrast, the IPM-CS group experienced decreases of -40, -50, and - 50% at these respective time points. Statistical analysis highlighted significant differences between the groups (p = 0.017 at 1 month, p = 0.009 at 3 months, and





◄ Fig. 4 This series of line graphs depicts mean clinical outcomes following GAE using lipiodol compared to imipenem/cilastatin (IPM-CS) over a 6-month period. Outcomes include: A. Visual Analog Scale (VAS) for pain, B. Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) pain score, C. WOMAC function score, D. WOMAC stiffness score, and E. WOMAC total score, measured at baseline, 1 month, 3 months, and 6 months postprocedure

p = 0.002 at 6 months). Additionally, in the lipiodol group, a rise in WOMAC stiffness scores compared to baseline was observed in 2 patients at 1 month, 4 patients at 3 months, and 4 patients at 6 months. A significant change in WOMAC stiffness scores from pre-GAE to post-GAE was noted at the 1-month mark, but not at 3 or 6 months in the lipiodol group (p = 0.025 at 1 month, p = 0.334 at 3 months, and p = 0.521 at 6 months) (Fig. 4).

Discussion

In our study comparing the safety and efficacy of lipiodol and IPM-CS in GAE, both agents demonstrated comparable technical and clinical success rates. However, the lipiodol group exhibited higher WOMAC stiffness scores compared to the IPM-CS group.

Lipiodol, a radiopaque contrast medium, possesses embolic properties. It is frequently used in transcatheter arterial chemoembolization for treating liver tumors, serving dual functions: as a vehicle to enhance the localization of chemotherapeutic agents within the tumor and as an embolic agent to obstruct the tumor's blood supply, thereby inducing ischemia and reducing tumor size [9]. We capitalized on its temporary embolic properties in GAE for knee osteoarthritis [6].

In our study, lipiodol was used as a temporary embolic agent in GAE, and when compared to the IPM-CS group, no significant difference was observed in the incidence of mild and moderate adverse events. Casadaban et al., in their systematic review, reported transient skin erythema post-GAE without ulceration in 21 out of 186 (11%) participants, all of which resolved without intervention [15]. Notably, these events were more prevalent, occurring in 17 out of 27 (63%) procedures involving permanent microparticles with symptoms lasting one to three months, compared to a shorter duration of approximately three weeks in 4 out of 159 (2.5%) procedures using IPM-CS. Bagla et al. identified potential post-procedural neurological alterations, localized bone marrow edema, and skin discoloration [5]. Padia et al. observed self-limiting focal skin ulceration in seven patients and an asymptomatic bone infarct in two patients [16]. Min et al., in their study employing a quick-soluble gelatin sponge as the embolic

agent, documented this outcome in 49 out of 97 (50.5%) procedures [7]. In another study utilizing lipiodol conducted by Sapoval et al., 2 out of 22 (9%) patients experienced post-embolization adverse events; one had knee edema lasting four days, with associated erythema persisting for two days, while another experienced erythema in the target knee for four hours [6]. It is possible that Sapoval et al. observed fewer side effects due to their use of a mixture of lipiodol with iodinated contrast medium for embolization, which may have mitigated adverse reactions.

In the study by Sapoval et al., significant reductions in WOMAC stiffness scores were reported at the first and third months following GAE with lipiodol [6]. In contrast, our findings did not demonstrate a significant change in WOMAC stiffness scores at the third and sixth months in the lipiodol group, and interestingly, at the six-month mark, four patients had higher scores compared to baseline. Additionally, the IPM-CS group consistently showed significantly lower scores than the lipiodol group at the first, third, and sixth months. It is hypothesized that lipiodol, by preferentially perfusing smaller arterioles and consequently impairing the nutrient supply to adjacent musculature, may contribute to augmented joint stiffness in patients.

Regarding pain and functional assessments, no significant differences were noted between the lipiodol and IPM-CS groups in VAS pain, WOMAC pain, function, and total scores at the one, three, and six-month intervals. This parallels the findings of Min et al. and Padia et al., who defined clinical success as a greater than 50% reduction in VAS score, reporting rates at six months of 72.2% and 75%, respectively [7, 16]. Our study reflected similar rates, with the lipiodol group showing a success rate of 69.2% and the IPM-CS group a rate of 75.9%.

Although the technical success rate in the lipiodol group was 100%, operators reported greater challenges during lipiodol embolization. Key difficulties include a higher susceptibility to reflux and the unpredictable behavior of lipiodol droplets.

This study has some limitations, notably the small sample size of the lipiodol group and its retrospective nature. Additionally, the limited follow-up duration of 6 months precluded long-term outcome observations. Furthermore, the single-center setting and single-operator involvement may reduce the generalizability of our findings.

Conclusion

While lipiodol demonstrates a clinical success rate comparable to IPM-CS in GAE, it is observed that the WOMAC stiffness scores are consistently higher in the lipiodol group. Funding This study was not supported by any funding.

Data Availability No data that support the findings of this study are available.

Declarations

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

Ethical Approval All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

Informed Consent Informed consent was obtained from all individual participants included in the study.

Consent for Publication Consent for publication was obtained for every individual person's data included in the study.

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