ORIGINAL ARTICLE

EFFICACY OF BLEOMYCIN-LIPIODOL EMBOLIZATION IN TREATING SYMPTOMATIC GIANT HEPATIC VENOUS MALFORMATIONS

Semptomatik Dev Hepatik Venöz Malformasyonların Tedavisinde Bleomisin-Lipiodol Embolizasyonunun Etkinliği

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ABSTRACT

Objective: According to the 2018 ISSVA classification, most lesions previously termed hepatic hemangiomas are now categorized as slow-flow hepatic venous malformations (HVMs). Giant HVMs (>5 cm) may cause significant symptoms and complications. To evaluate the efficacy and safety of transarterial chemoembolization (TACE) with a bleomycin-lipiodol mixture in patients with symptomatic giant hepatic venous malformations.

Material and Methods: This retrospective study included 38 symptomatic patients (32 women, 6 men) with HVMs larger than 5 cm, treated between May 2020 and May 2022. Diagnosis was established using characteristic findings on contrast-enhanced computed tomography and/or magnetic resonance imaging and was supported by digital subtraction angiography. Lesion volume and symptoms were assessed pre-procedure and at 11-13 months post-treatment. Technical success was defined as selective embolization of all feeding arteries, and clinical success as symptom improvement with >50% volume reduction. Appropriate statistical analyses were performed to evaluate treatment outcomes.

Results: All procedures were technically successful. Mean baseline lesion volume decreased from 502.3 cm^3 to 138.4 cm^3 at one-year follow-up, a mean shrinkage of 72.4% ($p<0.001$). Clinical success was achieved in 94.7% of cases. Pain Visual Analog Scale scores decreased from 5.2 to 1.3 ($p<0.001$). No major complications occurred; three patients experienced transient post-embolization syndrome. Drug distribution grading significantly correlated with lesion shrinkage ($p=0.0059$), while sex, age, lesion location, and drug dose were not significant predictors.

Conclusion: Bleomycin-lipiodol TACE is a safe and effective minimally invasive treatment for symptomatic giant HVMs, achieving substantial lesion shrinkage and symptom relief with minimal complications.

Keywords: *Hemangioma; Hepatic Venous Malformation; Trans-Arterial Chemo-Embolization; Bleomycin; Lipiodol*

ÖZET

Amaç: 2018 ISSVA sınıflamasına göre, daha önce hepatik hemanjiyom olarak adlandırılan lezyonların büyük çoğunluğu günümüzde yavaş akımlı hepatik venöz malformasyonlar (HVM) olarak sınıflandırılmaktadır. Dev HVM'ler (>5 cm) belirgin semptomlara ve komplikasyonlara yol açabilmektedir. Bu çalışmada, semptomatik dev hepatik venöz malformasyonlu hastalarda bleomisin-lipiodol karışımı ile uygulanan transarteriyel kemoembolizasyonun (TACE) etkinlik ve güvenliğinin değerlendirilmesi amaçlandı.

Gereç ve Yöntemler: Bu retrospektif çalışmaya, Mayıs 2020 ile Mayıs 2022 tarihleri arasında tedavi edilen, 5 cm'den büyük HVM'ye sahip 38 semptomatik hasta (32 kadın, 6 erkek) dahil edildi. Tanı, kontrastlı bilgisayarlı tomografi ve/veya manyetik rezonans görüntülemedeki karakteristik bulgulara dayanılarak konuldu ve dijital substraksiyon anjiyografi ile desteklendi. Lezyon hacmi ve semptomlar işlem öncesinde ve tedaviden 11-13 ay sonra değerlendirildi. Teknik başarı, tüm besleyici arterlerin selektif embolizasyonu olarak; klinik başarı ise semptomlarda düzelme ile birlikte %50'den fazla hacim azalması olarak tanımlandı. Tedavi sonuçlarını değerlendirmek amacıyla uygun istatistiksel analizler yapıldı.

Bulgular: Tüm işlemler teknik olarak başarılıydı. Ortalama başlangıç lezyon hacmi 502,3 cm^3 iken, bir yıllık takipte 138,4 cm^3'e geriledi ve ortalama %72,4 küçülme sağlandı ($p<0,001$). Klinik başarı oranı %94,7 olarak bulundu. Ağrı Görsel Analog Skalası skorları 5,2'den 1,3'e düştü ($p<0,001$). Majör komplikasyon izlenmedi; üç hastada geçici post-embolizasyon sendromu gelişti. İlaç dağılım derecelendirmesi ile lezyon küçülmesi arasında anlamlı korelasyon saptandı ($p=0,0059$). Cinsiyet, yaş, lezyon lokalizasyonu ve ilaç dozu anlamlı prediktörler değildi.

Sonuç: Bleomisin-lipiodol ile uygulanan TACE, semptomatik dev HVM'lerde belirgin lezyon küçülmesi ve semptom gerilemesi sağlayan, minimal komplikasyon oranına sahip güvenli ve etkili bir minimal invaziv tedavi yöntemidir.

Anahtar Kelimeler: *Hemanjiyom; Hepatik Venöz Malformasyon; Trans-Arteryal Kemo-Embolizasyon; Bleomisin; Lipiodol*

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INTRODUCTION

According to the classification system updated by the International Society for the Study of Vascular Anomalies (ISSVA) in 2018, the majority of hepatic lesions previously referred to as hepatic hemangiomas are now classified as slow-flow venous malformations rather than true vascular tumors (1,2). Histopathologically, these lesions are composed of cavernous vascular spaces lined by flattened endothelium (3). Hepatic venous malformations (HVMs) represent the most common benign vascular lesions of the liver. They typically present as well-circumscribed hypervascular lesions and are more frequently observed in women, with a reported prevalence ranging from 0.4% to 7.3% based on autopsy studies and an incidence of 0.4-20% in the general population (4-6). Small and asymptomatic lesions are usually managed conservatively, whereas giant lesions (>5 cm) are associated with an increased risk of rupture and pain (7,8). Giant HVMs may cause significant symptoms due to local mass effect, including dysphagia or respiratory distress, abdominal pain, early satiety, and nausea, and more rarely may lead to serious complications such as hemorrhage, Kasabach-Merritt syndrome, or Budd-Chiari syndrome, thereby necessitating alternative therapeutic approaches (8,9). Intervention is generally considered for symptomatic lesions or those demonstrating progressive growth. In symptomatic giant lesions, surgical resection or enucleation has traditionally been regarded as the definitive treatment. However, surgical management is associated with substantial morbidity rates ranging from 13% to 21%, including risks of hemorrhage, bile leakage, infection, and prolonged hospitalization (10-13). To date, neither an established medical therapy nor an optimal timing for surgical intervention has been clearly defined, and liver transplantation is required only in rare cases (14,15). Consequently, minimally invasive treatment options have attracted increasing interest in recent years. Transarterial embolization has emerged as an alternative therapeutic option for symptomatic HVMs (16). Among the various embolic and sclerosing agents employed, the bleomycin-lipiodol combination has demonstrated favorable outcomes in terms of both efficacy and safety. Nevertheless, the reported adverse events and heterogeneous efficacy results underscore the need for a more comprehensive evaluation of this treatment modality. Bleomycin is a cytotoxic antibiotic that induces DNA strand breaks through free radical generation, disrupting cell division with pronounced effects on vascular endothelial cells (17). Following endothelial injury, inflammatory and fibrotic processes lead to vascular occlusion and lesion shrinkage which represents the desired therapeutic effect in vascular malformations (17,18). Bleomycin exerts predominantly localized effects with fewer systemic adverse events than other sclerotherapy agents. Its main complications include pulmonary fibrosis and mucocutaneous changes, with pulmonary toxicity risk increasing at high cumulative doses or with prolonged perioperative oxygen therapy (19,20). At low doses, tissue toxicity is limited, making bleomycin safe and effective for sclerotherapy (21). Bleomycin is often combined with lipiodol, an iodinated oil that enhances visualization under fluoroscopy and prolongs drug retention within HVM tissue through its oily nature, thereby improving treatment efficacy (22). This study aimed to evaluate the safety and efficacy of transarterial bleomycin-lipiodol embolization in adults with symptomatic giant HVMs, focusing on volumetric response, symptom improvement, and factors influencing outcomes.

MATERIAL AND METHODS

This retrospective study evaluated patients who underwent transarterial chemoembolization (TACE) with a bleomycin-lipiodol mixture between May 2020 and May 2022 at a tertiary academic hospital.

Inclusion criteria were as follows:

- HVM larger than 5 cm demonstrating imaging characteristics consistent with hepatic venous malformation
- Symptomatic patients
- Age older than 18 years

Exclusion criteria were:

- History of hepatic surgery
- Diagnosis of hepatic malignancy
- Patients with coagulopathy
- Absence of appropriate follow-up imaging
- Angiographic features inconsistent with typical HVM

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A total of 38 patients (32 women, 6 men; mean age: 51±7.7 years) were included in the study. The diagnosis was established solely on the basis of characteristic imaging findings, without histopathological confirmation. In all patients, hepatic lesions were evaluated using either triphasic contrast-enhanced computed tomography (CT) or dynamic gadolinium-enhanced magnetic resonance imaging (MRI), and the imaging features were considered consistent with HVMs.

On triphasic CT, the lesions demonstrated the following characteristics:

- Hypodensity on non-contrast images,
- Peripheral, discontinuous nodular enhancement during the arterial phase,
- Progressive centripetal fill-in during the portal venous and delayed phases,
- Isoattenuation or mild hyperattenuation relative to the surrounding liver parenchyma on delayed-phase images (23,24).
- On dynamic contrast-enhanced abdominal MRI, the lesions were characterized by:
- Hypointense signal on T1-weighted images,
- Markedly hyperintense signal on T2-weighted images (“light-bulb bright” appearance),
- Peripheral nodular enhancement with progressive centripetal filling on post-contrast dynamic sequences, consistent with CT findings.

No imaging features suggestive of malignancy such as early or delayed washout, capsular enhancement, diffusion restriction, or an infiltrative growth pattern were observed in any of the lesions (25,26).

Previous studies have reported that contrast-enhanced CT and MRI demonstrate a diagnostic accuracy exceeding 95-98% for hepatic hemangiomas with typical imaging features, with T2-weighted MRI showing a sensitivity of up to 98% and a specificity approaching 99%. Accordingly, histopathological confirmation is generally considered unnecessary in the presence of characteristic imaging findings (9).

In the present study, histopathological sampling was not performed.

The primary reasons for this approach were:

1. The substantial risk of severe hemorrhage associated with biopsy of vascular lesions,
2. The high diagnostic reliability of contemporary imaging modalities, and
3. Ethical considerations regarding the performance of an invasive procedure that would not contribute additional diagnostic value (27,28).

Prior to the intervention, digital subtraction angiography (DSA) was performed in all cases and demonstrated characteristic late arterial-parenchymal enhancement with persistent nodular contrast pooling extending into the venous phase, supporting the imaging-based diagnosis established by CT and MRI (9).

Using a multimodal imaging approach combined with clinical correlation, alternative diagnoses; including hepatocellular carcinoma, hypervascular metastases, focal nodular hyperplasia, hepatic adenoma, and arteriovenous shunts were excluded.

HVM volume and lesion number were assessed using triphasic CT or dynamic contrast-enhanced MRI. Lesion volumes were quantified by three-dimensional segmentation of the lesions using 3D Slicer software.

Pre-procedural laboratory evaluations included complete blood count, liver function tests (ALT, AST, GGT), and coagulation profiles. All patients had INR <1.5, and platelet counts >50,000/mL.

All patients received pre-procedural analgesics, antiemetics, proton pump inhibitors, and prophylactic intravenous cefazolin (1 g).

Technical success was defined as selective delivery of the bleomycin-lipiodol mixture into the feeding arteries without non-target embolization, and complete embolization of all lesion feeders.

Clinical success was defined as symptom relief following TACE and >50% reduction in lesion volume on follow-up imaging compared to baseline.

All procedures were performed by two interventional radiologists with 4 and 8 years of experience. Under sterile conditions and local anesthesia, common femoral artery puncture was performed using an 18G needle, and a 5F femoral sheath (Cordis, Miami, FL, USA) was inserted. Angiography of the celiac trunk and superior mesenteric artery was performed using a 5F Simmons 1 catheter (Boston Scientific, Natick, MA, USA). Lesion typically demonstrated dense, nodular opacification within dilated vascular spaces starting in the late arterial/hepatic parenchymal phases and persisting into the venous phase (3). Characteristic

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angiographic findings confirmed the imaging-based diagnosis prior to embolization.

Feeding arteries were identified, and a 2.4 Fr Progreat coaxial microcatheter (Terumo Corporation, Tokyo, Japan) with a 0.016-inch guidewire was advanced superselectively. A single vial of bleomycin sulfate [Bleocin-S, 15 mg (15,000 IU); Onko/Koçsel, Türkiye] was dissolved in 5 mL saline and mixed with 15 mL lipiodol (Laboratoire Guerbet, France) using a three-way stopcock, yielding a 20 mL emulsion. The emulsion was slowly injected through the microcatheter using a 2 mL locking syringe, with careful monitoring to prevent reflux. The maximum bleomycin dose per session was limited to 15,000 IU. Embolization was completed once all feeding arteries were occluded. Completion hepatic arteriography confirmed complete embolization and assessed the distribution of the bleomycin-lipiodol mixture within the lesion. The distribution of the embolic mixture along the lesion rim was graded on a four-point scale (29):

- Grade 1: <25% coverage of the lesion rim
- Grade 2: 25-50% coverage
- Grade 3: 50-75% coverage
- Grade 4: >75% coverage

Patients were monitored for at least 24 hours post-procedure and discharged within 24-48 hours if no complications occurred. Three patients developed transient post-embolization syndrome (pain, nausea, vomiting), which resolved within 72 hours with supportive treatment. No major complications were observed. All patients provided written informed consent after counseling regarding the procedure and surgical alternatives. Treatment response was evaluated at 11-13 months post-TACE using contrast-enhanced MRI or CT. Lesion volumes were compared with baseline measurements, and pain severity was assessed using the Visual Analog Scale (VAS). The study was approved by the Institutional Review Board [decision no: 155, date: May 20, 2022] and conducted in accordance with the Declaration of Helsinki. Statistical analyses used R software (v3.6.0). Continuous variables were reported as mean±SD or median (IQR); categorical as frequencies. Normality was tested via Shapiro-Wilk. Paired t-tests or Wilcoxon signed-rank tests compared continuous variables; McNemar's test evaluated categorical changes. Associations were assessed using chi-square, Pearson, or Spearman correlations. Multivariate linear and logistic regression identified independent predictors of volume reduction and pain relief, including age, sex, drug dose, lesion location, and distribution grading. Significance was set at $p<0.05$.

RESULTS

A total of 38 patients were included in the study, comprising 32 women and 6 men. The mean age was 51±7.7 years (95% CI: 48.5-53.5), and the mean drug volume administered per procedure was 14.9±2.9 mL (95% CI: 13.9-15.9). HVMs were located in the right hepatic lobe in 24 patients and in the left lobe in 14 patients. The most common baseline HVM volume range was 100-500 cm^3, accounting for 57.9% of cases (Table 1).

Table 1. Frequency and mean±standard deviation (SD) of patient's basic characteristics

Variable	Group	Frequency	Percent (%)
Sex	Male	6	15.8%
	Female	32	84.2%
Age	<50	18	47.4%
	≥50	20	52.6%
Location	Right lobe	24	63.16%
	Left lobe	14	36.84%
Drug coverage grade	Grade 1	0	0.0%
	Grade 2	3	7.9%
	Grade 3	10	26.3%
	Grade 4	25	65.8%

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Table 1. Continued

Preoperative volume	<100 cm³	1	2.6%
	100-500 cm³	22	57.9%
	500-1,000 cm³	13	34.2%
	>1,000 cm³	2	5.3%

SD: Standard deviation

A statistically significant reduction in HVM volume was observed after treatment (p<0.001). The mean baseline volume decreased from 502.3±288.3 cm³ (95% CI: 407.3-597.3) to 138.4±95.9 cm³ (95% CI: 106.8-170.0) at the 1-year follow-up, corresponding to a mean volume reduction of 72.4% (95% CI: 66.1-78.7), indicating substantial treatment efficacy. The most frequently observed reduction range was 60-69% (31.6% of patients), and only two patients (5.3%) exhibited a volume reduction of less than 50%. The clinical success rate was 94.7% (95% CI: 82.3-99.4). A strong positive correlation was identified between baseline and 1-year follow-up volumes (r=0.87). The distribution of volume reduction is presented in Table 2, while pre- and post-treatment volumes are illustrated in Figure 1.

Table 2. Volume shrinkage (n:38)

Group	Frequency	Percent (%)
<50%	2	5.3%
50-59%	2	5.3%
60-69%	12	31.6%
70-79%	9	23.7%
80-89%	10	26.3%
>90%	3	7.9%

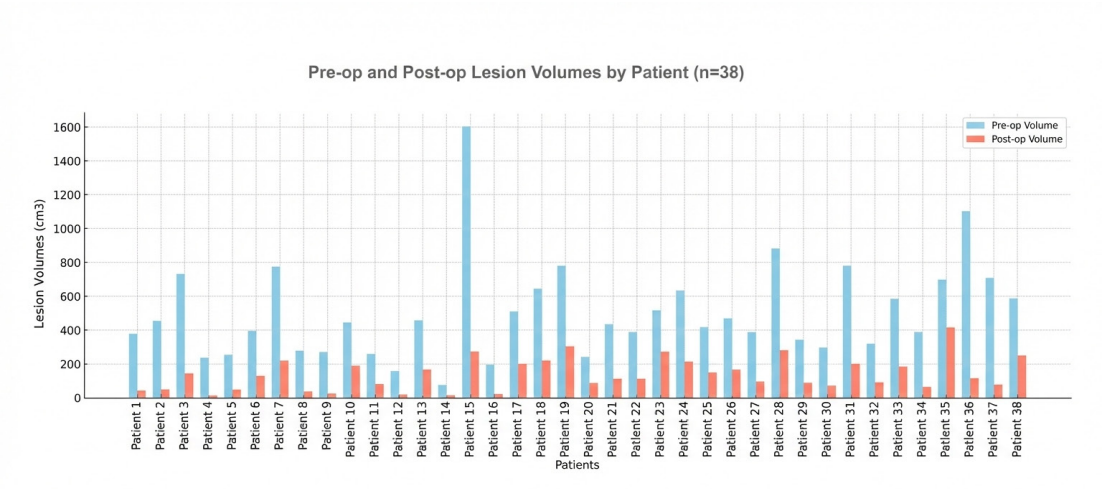

Figure 1. Lesion volumes before TACE and at 1-year post-procedure follow-up
TACE: Transarterial chemoembolization

At baseline, pain was reported by 34 patients (89.5%), most commonly in the right hypochondrium and lumbar regions, while early satiety occurred in 4 patients. Mean VAS scores decreased significantly from 5.2 to 1.3 ($p<0.001$). The degree of pain reduction varied significantly by localization ($p<0.05$), with the greatest improvement observed in left hypochondrial pain and the least in epigastric pain.

The relationship between HVM volume reduction and pain relief was evaluated using Spearman correlation analysis. Although a weak negative correlation was observed, it did not reach statistical significance ($\rho=-0.15$; $p=0.41$). Similarly, a weak, negative, but statistically nonsignificant correlation was found between age and the degree of HVM volume reduction ($r=-0.268$; $p=0.104$). Independent-samples t-test analysis revealed no significant difference in volume reduction rates between sexes ($p=0.61$). No significant difference was observed according to HVM lobe localization ($p=0.55$; Figure 2A). The association between embolic distribution grade and HVM volume reduction was analyzed using the Kruskal-Wallis test, which demonstrated statistically significant differences across distribution grades ($H=10.27$; $p=0.0059$; Figure 2B). In contrast, no significant association was identified between the administered drug volume and the degree of volume reduction ($p=0.12$).

Representative pre- and post-treatment imaging findings illustrating the typical volumetric response to therapy are shown in Figures 3 and 4.

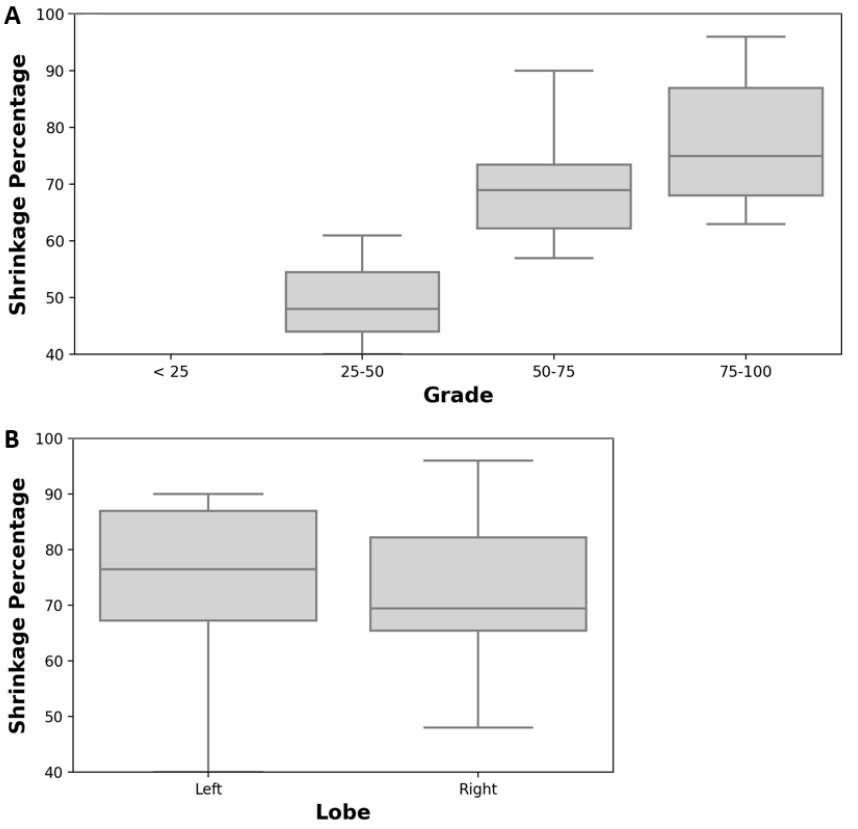

Figure 2 A-B. A) Box plot of shrinkage percentage and drug coverage grade in lesion, Increasing drug coverage grade was consistent with higher shrinkage percentage of lesion among grade 3 and 4. **B)** Box plot of lesion shrinkage in different liver lobes

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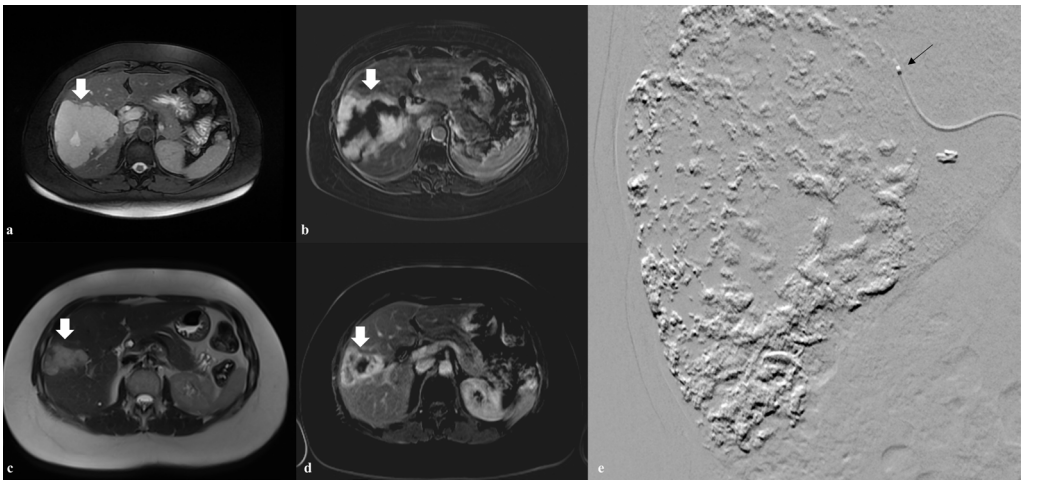

Figure 3. A patient presenting with early satiety and dyspeptic complaints was found to have a lesion in the left lobe of the liver, indicated by the arrow. After the procedure, the patient experienced marked symptomatic improvement. A) Preoperative axial T2-weighted image. B) Preoperative axial contrast-enhanced T1-weighted image. C) Postoperative axial T2-weighted image. D) Postoperative axial contrast-enhanced T1-weighted image. C, D) Postoperative images demonstrate a significant reduction in lesion size. E) Angiographic image showing complete embolization of the lesion through a super-selective microcatheter approach (thin white arrow), using a bleomycin-lipiodol mixture delivered into the feeding artery

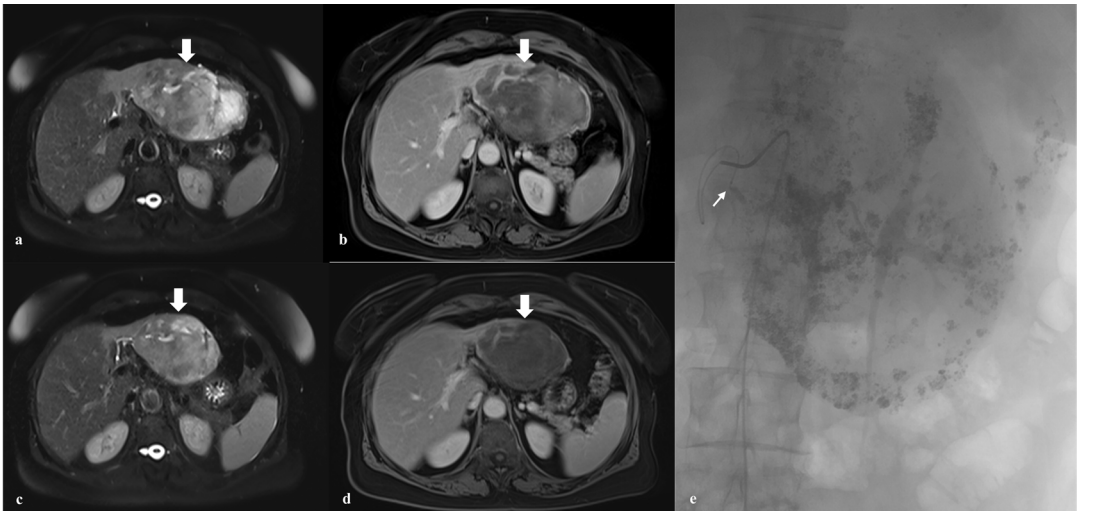

Figure 4. A patient presenting with right hypochondrial pain was found to have a lesion in the right lobe of the liver, indicated by the thick white arrow. Following the procedure, the patient's symptoms improved. A) Preoperative axial T2-weighted image. B) Preoperative axial contrast-enhanced T1-weighted image. C) Postoperative axial T2-weighted image. D) Postoperative axial contrast-enhanced T1-weighted image. C, D) Postoperative images demonstrate a marked reduction in lesion size. E) Angiographic image showing complete embolization of the lesion through a super-selective microcatheter approach (thin black arrow), using a bleomycin-lipiodol mixture delivered into the feeding artery

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DISCUSSION

The role of TACE in the management of giant HVMs remains incompletely defined, with no consensus on treatment indications or optimal chemotherapeutic agents (30). While surgical resection or enucleation is effective, it carries high morbidity risk, limiting its use as first-line therapy (31).

A comprehensive meta-analysis by Torkian et al. (2021) compared bleomycin-lipiodol based and non-bleomycin TACE regimes with respect to Lesion volume reduction, symptomatic improvement, and complication rates (30). While no significant differences were observed in symptom relief or complications, lipiodol based regimes achieved significantly greater Lesion volume reduction ($p<0.001$).

In recent years, Various embolic agents, including polyvinyl alcohol, ethanol, gelatin sponge, and bleomycin, have been used in TACE for HVMs. However, non-selective agents such as ethanol and polyvinyl alcohol have been associated with severe pain and non-target embolization, whereas gelatin sponge alone may be insufficient for effective venous sinusoid obliteration (14).

Bleomycin-lipiodol combination provides both embolic and sclerosing effects. While lipiodol selectively accumulates within vascular sinusoids and serves as a carrier, bleomycin induces endothelial injury and subsequent fibrosis, leading to devascularization and sustained lesion shrinkage (18).

Furumaya et al. (2019) published a comprehensive review encompassing 18 studies and a total of 1,284 patients with giant hepatic hemangiomas (HHs) (10). The review reported promising outcomes in terms of both lesion shrinkage and symptomatic improvement and emphasized that the potential role of TACE in the management of HHs should be reconsidered.

In a large-scale analysis evaluating surgical interventions for HHs, symptomatic improvement rates ranged between 44% and 87%. In contrast, patients treated with TACE demonstrated partial or complete symptomatic improvement in 98.5% of cases. Major surgical complications, including hemorrhage, bile leakage, and liver failure, were reported at rates of 1.8-5.1%, whereas the overall complication rate following TACE was 2.9%. Notably, no mortality was observed in patients undergoing TACE, while a mortality rate of 0.2% was reported in the surgical group (10).

Although complications such as liver failure, infarction, hemorrhage, and sclerosing cholangitis have been reported after TACE, these events are rare and mostly described in isolated cases or large series (32). In a recent study on giant HVMs, post-embolization syndrome occurred in 45.7% of patients, while no treatment-related mortality was observed, and substantial volume reduction (>75%) was achieved in 77.5% of cases (8).

In our study, mean lesion volume decreased from 502.3 to 138.4 cm^3, and VAS scores from 5.2 to 1.3 (both $p<0.05$), consistent with the literature.

Although many HVMs remain asymptomatic, abdominal pain is the most common presenting symptom in symptomatic patients. The pathogenesis is multifactorial, including stretching of the Glisson capsule, intralesional complications (hemorrhage, thrombosis, necrosis), and compression of adjacent organs (3). In the present study, no significant correlation was observed between volume reduction and pain improvement, suggesting that symptom relief may depend on volume-independent mechanisms such as reduced intralesional pressure and altered venous drainage. Accordingly, decreased capsular tension and relief of organ compression may account for clinical improvement even in cases with limited volumetric response.

Abdominal pain in patients with hepatic hemangiomas should be interpreted with caution, as alternative etiologies may coexist. Comprehensive evaluation to exclude other pathologies is essential before attributing symptoms to the lesion and proceeding

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with treatment. Farges et al. (1995) evaluated 87 patients with abdominal pain and HH and identified an alternative cause of pain in 54% of cases. Notably, among the 14 patients who underwent HH-directed treatment, symptoms persisted in half, suggesting that pain was not directly attributable to the hemangioma in a substantial proportion of patients (33).

Similarly, a previous TACE study demonstrated that marked volumetric response does not necessarily translate into complete symptomatic relief. Despite approximately fourfold volume reduction, persistent or partial pain was reported in some patients, supporting the notion that initial pain may have been unrelated to the hemangioma (34).

Consistent with these findings, Leon et al. (2020) reported that the majority of patients presenting with both abdominal pain and giant HH had symptoms attributable to gastrointestinal comorbidities, including irritable bowel syndrome, gastroesophageal reflux disease, peptic ulcer disease, hepatitis, and gallbladder disorders. Only 21.7% of symptomatic patients had pain that could be directly attributed to the hemangioma itself (9).

Study Limitations

This study has several limitations. Its retrospective design and relatively small sample size limit the generalizability of the findings to broader patient populations. The one-year follow-up period does not allow for assessment of long-term outcomes or potential recurrence. As all procedures were performed at a single center, the external validity of the results may be limited. Although the diagnosis was based on well-defined imaging characteristics, the lack of histopathological confirmation represents another limitation. Finally, the absence of a control group makes it difficult to attribute the observed changes exclusively to bleomycin-lipiodol embolization.

CONCLUSION

In conclusion, bleomycin-lipiodol embolization represents a safe and effective minimally invasive treatment option for symptomatic giant hepatic venous malformations. The combination of a low complication rate with substantial lesion volume reduction and significant symptomatic relief supports its role as a viable alternative to surgery in appropriately selected patients. Future studies should include larger patient cohorts and be designed as prospective, randomized controlled trials. In addition, multicenter studies involving different institutions and operators would enhance the generalizability of the results and help reduce potential biases.

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