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Efficacy of Transarterial Bleomycin-Lipiodol Embolisation in Patients with Giant Hepatic Hemangioma

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Abstract

Introduction :This study aimed evaluate symptom resolution, size reduction and complications of transarterial chemoembolization (TACE) with Bleomycin-Lipiodol in giant liver hemangiomas.

Materials and Methods: This single-center study evaluated 19 consecutive patients with giant hepatic hemangioma who underwent transarterial chemoembolization between June 2020 and May 2023. Inclusion criteria were as follows: (1) presence of a hepatic mass larger than 5 cm on dynamic cross-sectional examination with typical features of a hemangioma, (2) presence of symptoms secondary to hepatic hemangioma or compression effect of the mass on surrounding tissues, (3) TACE procedure performed in our center. Clinical success was defined as resolution of symptoms and radiologic success was defined as more than 50% reduction in giant hemangioma volume on 6 months follow-up CT or MRI compared to baseline images.

Results: A total of 19 patients were included in the study. The mean size of hemangiomas decreased from 9.35cm±3.5cm (5cm-16.9cm) to 5.76cm±1.52cm (3.5cm-9cm). The volume of hemangiomas before the procedure was between 27 cc-845 cc with a median value of 169 cc. After the procedure, the volumes ranged between 14 cc-182 cc with a median value of 45 cc. The changes in both size and volume before and after the procedure were found to be significant and $p<0.0001$. Radiological success, more than 50% reduction in volume, was achieved in sixteen patients (84.2%). Significant improvement in symptoms and other signs of compression was also achieved in this group.

Conclusions: Liver hemangioma embolisation with Bleomycin-Lipiodol is safe, reduces the size and volume of giant liver hemangiomas, and provides significant success both clinical and radiological results.

Key words: Liver; hemangioma; bleomycin-lipiodol; embolization.

Introduction

Liver hemangiomas are vascular malformations consisting of endothelial cells arising from the hepatic artery. These tumours, which constitute approximately 1-20% of all liver tumours, are among the most common benign lesions of the liver (1). The most common pathological form is cavernous hemangioma, which is generally observed more frequently in women. Most hepatic hemangiomas develop in small sizes and asymptomatically, so they are detected incidentally and follow-up is usually recommended. However, giant hepatic hemangiomas over 5 cm in diameter tend to become symptomatic and lead to serious complications. These complications include rupture, hemorrhage, local compression, Kasabach-Merritt syndrome and Budd-Chiari syndrome. Especially chronic abdominal pain and compression findings are the main reasons for the need for treatment in these cases (2). Treatment options include corticosteroids, radiotherapy, cytotoxic agents and surgical treatments (2,3). However, transarterial chemoembolisation (TACE) is currently one of the most preferred methods in the treatment of giant hepatic hemangiomas (4-6). TACE, which is a minimally invasive method, stands out by having a lower risk of complications compared to the surgical approach, as well as significantly shortening the duration of hospitalisation. During the procedure, an active biological agent is used together with an embolising agent. While bleomycin used in this study provides non-specific inhibition and destruction of endothelial cells in the hemangioma (1), lipiodol, which has radiopaque and embolising properties, both provides ease of imaging and acts as a carrier for the chemotherapeutic agent. Lipiodol prevents tumour nutrition, causing ischaemia and subsequent reduction in tumour size. This combination is preferred because it acts locally on tumour tissue and minimises systemic exposure (7). The aim of this study was to evaluate the safety and feasibility of transarterial chemoembolisation (TACE) using a combination of bleomycin and lipiodol in patients with giant hepatic hemangioma. In particular, clinical

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outcomes such as symptom improvement and tumour size reduction were evaluated to investigate whether TACE is an effective treatment option in this patient group.

Materials and Methods

This retrospective study evaluated 19 consecutive patients with giant hepatic hemangioma who underwent transarterial chemoembolisation (TACE) between June 2020 and May 2023. This retrospective study involving human participants was conducted in accordance with the ethical guidelines. The aim of the study was to evaluate the safety and efficacy of TACE in patients with giant hepatic hemangioma.The inclusion criteria were; (1) the presence of a hepatic mass larger than 5 cm on dynamic cross-sectional examinations, with typical features of a hemangioma such as peripheral nodular contrast enhancement in the arterial phase and increased contrast enhancement towards the centre in the venous-late venous phase, (2) the presence of clinical symptoms due to hepatic hemangioma or compression effect of the mass on the surrounding tissues, (3) the TACE procedure was performed in between June 2020 and May 2023. Exclusion criteria included the absence of peripheral nodular contrast enhancement on arteriography, which is a typical vascular feature of hemangioma, and the inability to make a definitive diagnosis on imaging. Before the procedure, the patients were informed in detail and written informed consent was obtained. In addition, routine biochemistry and hemogram tests were performed in all patients. Patients were premedicated with 50 mg ranitidine, 45.50 mg pheniramine hydrogen maleate and 10 mg metoclopramide before the procedure. The procedure starts with the insertion of a vascular sheath (5F or 6F) into the femoral artery with an 18G needle after local anaesthesia. The celiac trunk and superior mesenteric artery were then selectively catheterised with a 5F Simon 1/Cobra 2 catheter and angiograms were obtained to determine the feeders of the lesion. A Progreat 2.7Fr/2.9Fr or Renegade 2.8Fr/3.0Fr coaxial microcatheter was then inserted into the feeding artery of the lesion. Superselective angiograms were also obtained from the microcatheter. In this way, the degree of coverage of the hemangioma margins was accurately assessed.

Under fluoroscopy, For TACE, combination of Lipiodol (Guerbet, France) with bleomycin sulphate (Bleosin-s ONKO-Koçsel, Turkey) was used as embolizing agent at 2:1 ratio in 5 mL saline solution.Then, a slow injection was made into the hemangioma through the microcatheter with a locked injector system. The procedure was terminated when as many sinusoids of the hemangioma as possible were filled. The amount of lipiodol was selected according to the diameter of the hemangioma and applied as 1 cc per cm. The maximum amount did not exceed 15 cc. The feeding arteries of the lesion were not embolised with a different emboliser. The final angiogram showed reduced or absent contrast enhancement of the hemangioma. After the procedure, the presence and severity of symptoms such as fever, nausea, abdominal pain and fatigue, which may be significant in terms of post embolisation syndrome, were closely monitored. We also carefully observed and recorded any serious adverse events that might occur during or after the procedure. Post-procedure pain severity was assessed using a comprehensive four-point Verbal Rating Scale (VRS). Scoring correlated with the analgesic strength required for effective analgesia. Patient information on the basis of scoring is shown in Table 2 (Table 2).In scoring, patients were divided into 2 separate groups according to the volume of hemangioma. Group 1 was divided into those with a volume of less than 100 cm3 (5 patients) and group 2 was divided into those with a volume of more than 100 cm3 (14 patients). The scores are as follows: 0 = no pain, 1 = mild pain requiring acetaminophen (paracetamol), 2 = moderate pain requiring ketoprofen, and 3 = severe pain requiring opioids. Using these comprehensive assessment criteria, we aimed to maximise the safety and well-being of patients throughout the treatment process. After discharge, our patients were followed up at 6 months and 12 months. Upper abdominal MRI without contrast and routine biochemistry examinations were performed for size change of the lesions. Demographic information of the patients such as gender, age, lesion localisation, oral contraceptive use, off-target embolisation, pre-procedure mass size and mass size reduction rates in the follow-up, change in pre-procedure symptoms in the follow-up (change in pain score VRS) were also examined.

Ethical approval: This study was approved by the Ethics Committee of Health Sciences University, Trabzon Medical Faculty, Scientific Research Projects Division (Decision No: 10496660-154; Date: 24/12/2024).

Statistical analysis: All of the data were analyzed using the Statistical Package for the Social Sciences (SPSS 25.0 Statistical Software, SPSS Inc., Chicago, IL, USA). Descriptive statistics, including the means, medians and ranges, were

Table 1: Frequency and mean ± standard deviation (SD) of baseline characteristics of patients

Categorical variables	Group	Frequency of lesions	Percent
Gender	Women	14	73.6
	Men	5	26.4
Age	40-50 years	8	42.1
	> 50 years	11	57.9

Table 2: Severity of pain in the post-embolisation syndrome. grade 0: no pain.

Categorical variables	Group	Frequency of lesions	Percent
Gender	Women	14	73.6
	Men	5	26.4
Age	40-50 years	8	42.1
	> 50 years	11	57.9
Preoperative* diameter	9.35±3.5cm(5-16.9cm)		
	< 10 cm	14	73.7
	> 10 cm	5	26.3
Preoperative* volume	27-845 cm3(median 169 cm3)		
	< 100 cm3	5	26.3
	100-1000 cm3	14	73.7
Postoperative* diameter	5.76±1.52cm(3.5-9cm)		
Postoperative* volume	14-182 cm3(median 45 cm3)		
Lob	Right	10	0.69
	Sol	9	0.31
Percentage of downsizing	>50%	16	84.2

***** The changes in both size and volume before and after the procedure were found to be significant and $p<0.0001$

calculated for numeric variables. Normality of the data was assessed by using the Kolmogorov-Smirnov test. Differences between VRS, volumes and longest diameters of liver hemangiomas were evaluated using paired-t test. A p value of less than 0.05 was considered to indicate a significant difference.

Results

Clinical information and imaging findings of all patients were recorded at follow-up. The mean age of 19 patients was 54.2 ± 10.5 years (range 40-72 years). In the study, the technical success rate was recorded as 100%, while clinical success was 84.2% (16 patients). Clinical success was defined as alleviation or complete resolution of symptoms and significant reduction in tumour size. In the early post-procedure period, transient symptoms compatible with post-embolisation syndrome (PES) such as fever, nausea, vomiting and pain were observed in 6 patients. It was noted that patients who developed PES had a longer hospitalisation period. The mean length of hospitalisation was 3.42 days; the shortest hospitalisation was 2 days (in 13 cases) and the longest was 9 days. It was noted that PES usually

resolves within a few days after the procedure, but pain and other symptoms in patients with PES require management. In addition to PES, comorbid conditions of the patients may also be effective in prolonged hospitalisation.Clinical success was defined as alleviation or complete resolution of symptoms and significant reduction in tumor size.Table 1 shows the characteristics of hemangiomas in different patients treated with bleomycin-lipiodol TACE The majority of our patients (12 patients) with giant hemangioma (largest diameter 16.7 cm) had abdominal pain at different localisations at least once before undergoing transarterial bleomycin-lipiodol TACE with a rate of 63.1%. Of the 12 patients who complained of pain (VRS score in the range of 1-3) before the procedure, 9 (75%) had no pain after the procedure, while in 3 of them, pain intensity (VRS score 1) decreased but remained mild. The change in VRS score was found to be significant and the p value was calculated as 0.002. The level of pain that developed during and after the procedure was categorised according to drug requirements. In the examination, 5 patients with a volume of less than 100 cm3 (Group 1) had no pain that required medication in the periprocedural phase, while 9 of 14 patients (64.2%) with a volume of more than 100 cm3 (Group 2) had pain that required medication. The findings are summarised in Table 2. The volume of bleomycin-lipiodol mixture used was minimum 4 cc, maximum 10 cc and median value was 10 cc.

	DEGREE 0	DEGREE 1	DEGREE 2	DEGREE 3
GROUP 1 (5 patients)	4 (%80)	1 (%20)	0	0
GROUP 2 (14 patients)	5 (%35,7)	6 (%42,8)	3 (%21,4)	0

Grade 1: Mild pain requiring administration of acetaminophen (paracetamol).
Grade 2: Moderate pain requiring ketoprofen administration.
Grade 3: severe pain requiring opioid administration

Discussion

Although studies on the efficacy and safety of transarterial chemoembolisation (TACE) in the treatment of giant hepatic hemangiomas are limited, the findings obtained in this study are consistent with other studies in the literature. When evaluated symptomatologically, it is known that most hepatic hemangiomas do not cause any complaints. Therefore, conservative management is preferred. However, giant hepatic hemangiomas may cause local compression, persistent pain and life-threatening complications such as Kasabach-Merritt syndrome, Budd-Chiari syndrome or rupture. Mortality rates up to 70% have been reported in case of complications (8,9,10). There is no complete agreement between interventional radiology and general surgery disciplines in terms of treatment algorithm. The size of the hemangioma, multifocal or multicentricity, location and the presence of accompanying possible complications are decisive in determining the treatment option. (11-13). The presence of complications with the risk of mortality and morbidity brings surgical procedures to the forefront in treatment. These include different surgical procedures such as enucleation of the hemangioma, liver resection and liver transplantation. Especially in the presence of hemangiomas larger than 10 cm located in the central part of the liver, enucleation surgery is superior to other methods and can be preferred. (14-16). However, the complications of enucleation surgery such as massive blood loss, long surgical time and hospitalisation period as well as surgical and postoperative complications such as bile leakage, ileus, gastrointestinal bleeding and wound infection make the treatment controversial (1,17). Radiofrequency ablation (RF), a non-invasive method, has been proposed as an effective alternative treatment for hepatic hemangioma. RF ablation is known to have significant shortcomings that make it inapplicable in hepatic hemangiomas larger than 7 cm, but it has been found to be ineffective in 60% of hepatic hemangiomas larger than 10 cm (18-19). Transarterial embolisation (TAE), which may be another treatment method, is a superselective embolisation and can be performed using jelfoam, microkiller and polyvinyl alcohol (PVA) (18,19). Yamamoto first reported preoperative TAE of a giant ruptured hemangioma (20). Since then, TAE has been used to treat diffuse hemangiomatosis and symptomatic hemangiomas in adults (21). Srivastava et al. reported eight patients treated with TAE. In seven of the patients, symptoms were completely resolved in 9 months, while one patient underwent surgery when the desired response was not observed.(22). Although the short-term complication risk of TAE seems to be

low, reports of long-term complications such as hemangioma recurrence, liver failure, embolisation of non-target areas and post-TAE syndrome due to failure to achieve optimal reduction in lesion size have made TAE a less preferred option (22-24). Since bleomycin is known to have antimitotic, antiangiogenic and sclerosing effects, it has been used in the treatment of vascular anomalies. It causes degradation in DNA and triggers the inflammatory process around the lesion (25). Lipiodol has both carrier and embolising properties and facilitates drug distribution and efficacy in the target area when emulsified with bleomycin (7). With the distribution of the bleomycin-lipiodol mixture into the lesion with the TACE procedure, the endothelium of the pathological vascular structures in the hemangioma is gradually destroyed. Thus, micro thrombus formation in the sinuses of the hemangioma with the effect of lipiodol, fibrosis is triggered with the effect of belomycin and atrophy in the mass is provided (1). Bozkaya et al. performed TAC with bleomycin-lipiodol mixture in a study group of 26 patients with a total of 32 lesions. In addition to symptomatic improvement, they found a statistically significant decrease in the size of the lesions. In their study, the mean volume of hemangiomas was calculated as 446.28 ± 88 cm3 (range 3.39-1559 cm3) before embolisation and 244.43 ± 54.38 cm3 (range 94-967 cm3) after the procedure(11). In our study, lesion volumes before treatment were between 27 cm3 -845 cm3 with a median value of 169 cm3 . Post-treatment volumes ranged between 14 cm3 - 182 cm3 and the median value was calculated as 45 cm3. Statistically significant size reduction was similar in both studies. Possible complications of TAC with bleomycin-lipiodol mixture include bleeding, hepatic artery dissection, liver failure, hepatic infarction, bilioma, cholecystitis, sclerosing cholangitis, splenic infarction (9). However, these complications are rare and have been reported mostly in case reports or larger studies (26). In our study, entry site haematoma was found in 1 patient and regressed with medical treatment. A retrospective study by Yuan et al. reported that bleomycin-lipiodol mixed TAC for the treatment of giant hepatic hemangiomas was a safe and effective method. No mortality or serious complications were observed in the post embolisation period. However, in the study group of 196 patients, a high rate of 86.7% (170 patients) showed a reduction of >50% in the maximum diameter of the target lesions at 12-month follow-up (6). The most common side effect related to the procedure is postembolisation syndrome (PES). Clinically, it presents with symptoms such as abdominal pain, fever, nausea and vomiting, which are more common in the right upper quadrant (27).The pathogenesis of PES is not fully understood and it is thought to be caused by cytokine release initiated by tissue ischemia in the first plan and then triggered inflammatory processes. In a study conducted by Arkadiusz et al. with 73 patients, it was found that PES was observed in 45.7% of the patients (28). Bozkaya et al. reported that all 26 patients had mild to moderate postembolisation syndrome and the most prominent symptom was abdominal pain starting immediately after the procedure. Nausea was reported in 16 (61.5%) patients and fever not exceeding 37.5 degrees Celsius was observed in 8 (3.1%) patients (11).In our study, PES was observed in 6 of 19 patients and was found to be below the literature average. In our centre, patients were hospitalised for 2 nights after the TACE procedure, but this period may be prolonged in our patients who developed PES. PES was the most common cause of prolonged hospitalisation. While no serious complications related to the procedure were observed, inguinal haematoma was observed in 1 patient and it was confirmed that no pseudoaneurysm developed and it was expected to resorb. Retrospective design and limited number of patients are among the limitations of our study. In addition, the lack of long-term follow-up data after TACE procedure constitutes a limiting factor in evaluating the long-term efficacy of this method. In this context, prospective studies with large sample size are necessary to evaluate the long-term efficacy and safety of TACE.

Study limitations: This study has several limitations. First, its retrospective design restricted the scope and robustness of the evaluation. Second, the sample size was relatively small, limiting the generalizability of the findings. Additionally, long-term follow-up data were unavailable, as patients who became asymptomatic often did not return for follow-up visits. Finally, there was no control group to assess the effectiveness of emulsions with different ratios. In conclusion, further prospective studies with larger patient populations and long-term follow-up are necessary to better evaluate the safety and feasibility of transarterial bleomycin–lipiodol embolization in patients with giant hepatic hemangiomas.

Conclusion

TACE with bleomycin-lipiodol combination in the treatment of giant hepatic hemangioma reduced

the tumour size and provided a significant improvement in symptoms in the majority of patients. This treatment method stands out as a valuable option in the treatment of giant hepatic hemangiomas with its minimal invasiveness and low complication rates.

Ethical approval: This study has been approved by the Trabzon faculty of Medicine Ethics Committee in the meeting numbered on 2024/13, with the decision numbered 2024/154.

Written informed consent: İnformed consent was not required because the study was retrospective

Conflict of interest: The authors declare no competing interests.

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Authors contributions: Corresponding author, concept-design, writer. statistical analysis E:B.; data collection, literature review M.E.K.

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