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ORIGINAL ARTICLE

Transcatheter Arterial Embolisation of Renal Angiomyolipomas Using an Ethanol-Lipiodol Mixture

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ABSTRACT

Introduction: *This study aimed to evaluate the outcomes of transcatheter arterial embolisation (TAE) of renal angiomyolipoma (AML) with a mixture of ethanol and Lipiodol, and to identify the factors predicting treatment response.*

Methods: *We performed a retrospective review of all patients who underwent elective TAE of renal AML using ethanol and Lipiodol over a 7-year period at our institution. Patient demographics, the presence or absence of the tuberous sclerosis complex, renal AML tissue components, pre- and post-procedure renal AML volumes, procedure details, and clinical course were documented.*

Results: *We identified 32 patients (25 females and 7 males, mean age = 55.2 years) who underwent elective TAE for renal AMLs. All cases showed technical success; one major complication without the need for escalated management (3.1%) was identified. The mean volume reduction of renal AML after TAE was 59.8% (standard deviation = 25%) with a mean imaging follow-up duration of 23.8 months. A predominance of angiomyogenic components of the lesion was significantly associated with good treatment response (p = 0.002).*

Conclusion: *TAE of renal AML using a mixture of ethanol and Lipiodol is an effective and safe treatment option that significantly reduces AML volume. Predominance of angiomyogenic components of an AML predicts significant AML volume reduction after the procedure.*

Key Words: *Angiomyolipoma; Embolization, therapeutic; Kidney; Tuberous sclerosis*

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Contributors: All authors designed the study. HLC, KST and YYM acquired the data. HLC, KHW, SWS and PSFL analysed the data. HLC, KHW, KST and YYM drafted the manuscript. SWS and PSFL critically revised the manuscript for important intellectual content. All authors had full access to the data, contributed to the study, approved the final version for publication, and take responsibility for its accuracy and integrity.

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Data Availability: All data generated or analysed during the present study are available from the corresponding author on reasonable request.

Ethics Approval: This research was approved by the Joint Chinese University of Hong Kong–New Territories East Cluster Clinical Research Ethics Committee, Hong Kong (Ref No.: 2023.207). The requirement for informed patient consent was waived by the Committee due to the retrospective nature of the research.

中文摘要

使用乙醇—碘化油混合物經導管動脈栓塞腎臟血管平滑肌脂肪瘤

陳凱玲、黃健開、譚健成、文欣欣、沈兆華、李醒芬

引言：本研究旨在評估使用乙醇和碘化油混合物進行腎臟血管平滑肌脂肪瘤（AML）經導管動脈栓塞（TAE）的效果，並了解預測治療反應的因素。

方法：我們對本機構7年來使用乙醇和碘化油接受選擇性TAE治療腎臟AML的所有患者進行回顧性分析。我們記錄了患者的基本資料、是否有結節性硬化症、腎臟AML組織成分、術前和術後腎臟AML體積、手術細節和臨床病程。

結果：本研究共有32名因腎臟AML接受選擇性 TAE 的患者（25名女性和7名男性，平均年齡 = 55.2歲）。所有案例均顯示技術成功，有一例無需升級處理的重要併發症（3.1%）。TAE後腎臟AML的平均體積減少為59.8%（標準差 = 25%），平均影像學追蹤時間 23.8 個月後。病變的血管肌生成成分佔主導與良好治療反應有顯著相關（p = 0.002）。

結論：使用乙醇和碘化油混合物治療腎臟AML是一種有效且安全的治療選擇，可顯著減少AML體積。 AML 的血管肌生成成分佔主導地位預示手術後AML體積顯著減少。

INTRODUCTION

Renal angiomyolipoma (AML) is a benign mesenchymal neoplasm of the kidney. It is broadly classified into two types, either sporadic (80%) or associated with tuberous sclerosis complex (TSC) [20%] which is an autosomal dominant disease with multisystem involvement.[1,2] AMLs are composed of an angiomyogenic component (blood vessels and smooth muscle) and a lipomatous component (fat).[3] The diagnosis of renal AML is based on the presence of macroscopic fat.[4,5] The differential diagnosis includes fat- and calcification-containing renal cell carcinomas, which are unusual.[6,7] Therefore, a fat-containing renal lesion without calcifications or other atypical features can usually be diagnosed as AML based on its radiological features.

The major complication of AML is spontaneous tumoural rupture leading to retroperitoneal haemorrhage into the subcapsular and perirenal space (Wunderlich syndrome), which can be life-threatening.[8] Risk factors for tumour rupture include large size, multifocality, and aneurysm formation.[9,10] Once the greatest tumour dimension is >4 cm, there is a greater incidence of symptoms which include bleeding and flank pain.[9] In our institution, transcatheter arterial embolisation (TAE) is employed for the treatment of AML in acute haemorrhage due to spontaneous rupture and high-risk AMLs that are considered suitable for prophylactic treatment (i.e., lesion dimension >4 cm and/or tumoural aneurysm ≥5 mm) with multidisciplinary agreement for selected cases. There is increasing use of TAE as prophylactic treatment for non-ruptured AMLs, giving its advantages of a low complication rate, avoiding general anaesthesia, less invasiveness, renal function preservation, and satisfactory outcome,[11-13] defined as absence of residual tumoural stain on digital subtraction angiography (DSA).[14,15]

There are multiple embolisation agent options. In our institute, we use a 2:1 mixture of ethanol and Lipiodol. Our study aimed to identify the outcome of TAE of renal AML using this mixture, by documentation of the lesion volume reduction and any complications. We also aimed to identify any tumoural factors associated with volume reduction after embolisation.

METHODS

We retrospectively identified all consecutive cases of renal AML TAE at North District Hospital in Hong Kong from January 2016 to December 2022 by reviewing the electronic records of the radiology department. Cases which ethanol and Lipiodol were not used as the embolic agent were excluded. Cases of urgent TAE due to presentation with acute haemorrhage were also excluded as the primary aim for this group of patients is haemostasis instead of volume reduction of the lesion.

Patient demographics and clinical data were reviewed in the electronic health records, including sex, age, presence or absence of TSC, presenting symptom, renal function tests (before and after TAE), procedure details, and hospitalisation record.

AML volume and percentage reduction were assessed from the latest computed tomography (CT) or ultrasound (US) before and after embolisation. The tissue components of each AML were determined on the latest pre-embolisation CT by consensus from three radiologists (with 12, 5, and 4 years of experience, respectively), who were blinded to clinical details and classified each AML as predominantly angiomyogenic (>50% soft tissue and/or blood vessel components) or predominantly lipomatous (>50% fat components). AML volume was calculated based on the x-, y-, and z-axis diameters (i.e., width, height, and length, respectively) on CT or US examination, with the equation to calculate the ellipsoid volume of $v = xyz\pi/6$.

Embolisation Technique

Figure 1 illustrates the embolisation procedure. TAE was performed through the common femoral artery with a 5-Fr angiographic catheter. Flush aortography and renal arteriography were first performed using DSA to identify the location and number of renal arteries and the arterial supply to the AML (Figure 1a). The arterial feeder to the AML was selectively catheterised (Figure 1b). TAE was performed (Figure 1c) by injecting the ethanol-Lipiodol mixture into the arterial feeder with a 1-mL syringe intermittently. Then, renal arteriography was performed to confirm that there were no residual arterial feeders to the lesion. Angiographic success was achieved when vascular stasis and the absence of visible arterial feeding vessels resulted (Figure 1d). The total volume of mixture injected depended on the endpoint of angiographic stasis and absence or occlusion of other feeders, and should not reach the maximum volume allowed according to the patient's weight.

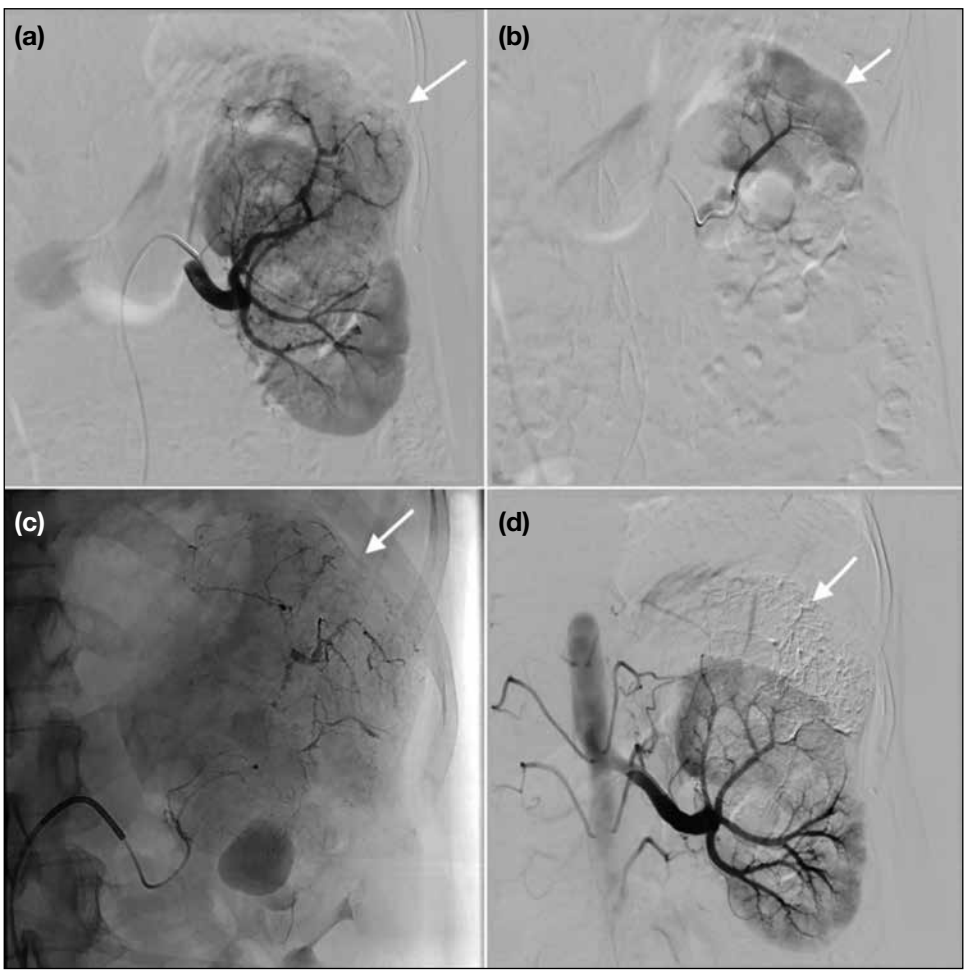

Figure 1. Arteriogram from a 59-year-old female patient with renal angiomyolipoma (AML). (a) Marked vascularity of the AML in the superior pole of the left kidney (arrow). (b) Selective catheterisation to the arterial feeder of the AML (arrow). (c) Transcatheter arterial embolisation of the AML in the superior pole of the left kidney (arrow) performed by injecting a mixture containing ethanol and Lipiodol in a ratio of 2:1. (d) Post-embolisation angiogram demonstrates complete non-opacification of the AML (arrow) and stasis of contrast flow to the lesion representing technical success.

Figure 2 illustrates technical non-success in the first round of TAE, with technical success after repeated embolisations. The angiographic catheter was then removed, and haemostasis was achieved by manual compression. After haemostasis at the puncture site was achieved, patients were transferred to the urology ward for observation and were usually discharged the day after the procedure if no major complications occurred.

Technical success, non-target embolisations, and major and minor complications were defined according to the quality improvement guidelines for TAE by the Society of Interventional Radiology (SIR) Standards of Practice Committee.[15] Technical success was defined as absence of residual tumoural stain on complete DSA. Major complications were defined as those events that resulted in prolonged hospitalisation, permanent renal damage, transfusion, or death. Minor complications included events that may have caused patient discomfort or some morbidity but did not meet the criteria for major adverse events.

Follow-up

Patients were followed up in the urology outpatient clinic of our hospital, with follow-up radiological examination including CT or US. Recurrence was defined as an increase in tumour volume on follow-up imaging and/or recurrent symptoms that required repeated TAE of the previously embolised tumour after 6 months of follow-up. Tumoural volume reduction of >50% after TAE was considered a good response, whereas reduction of ≤50% after TAE was considered a poor response.

Statistical Analysis

Statistical analysis was performed using commercial software SPSS (Windows version 26.0; IBM Corp, Armonk [NY], United States). Categorical variables were expressed as frequencies and percentages, and quantitative data were expressed as mean ± standard deviation (SD). Fisher's exact test was used to compare the categorical variables, and an independent sample *t* test was used to compare the continuous variables between groups. Pre- and post-procedure AML size and patient's creatinine levels were compared using a paired *t* test. A p value of < 0.05 were considered to indicate statistical significance.

RESULTS

We identified 32 patients eligible for the study, with a mean age of 55.2 years (range, 30-73). Among these patients, 25 (78.1%) were female and seven (21.9%) were male. Two (6.3%) patients were diagnosed with TSC (Table 1).

A mean volume of 3.61 mL (SD = 4.87) of the ethanol-Lipiodol mixture was injected for each AML. The average procedure time was 53.8 minutes (range, 22-143), with the starting time and ending time defined by the first and last fluoroscopy images. Clinical characteristics of the patients are summarised in Table 1.

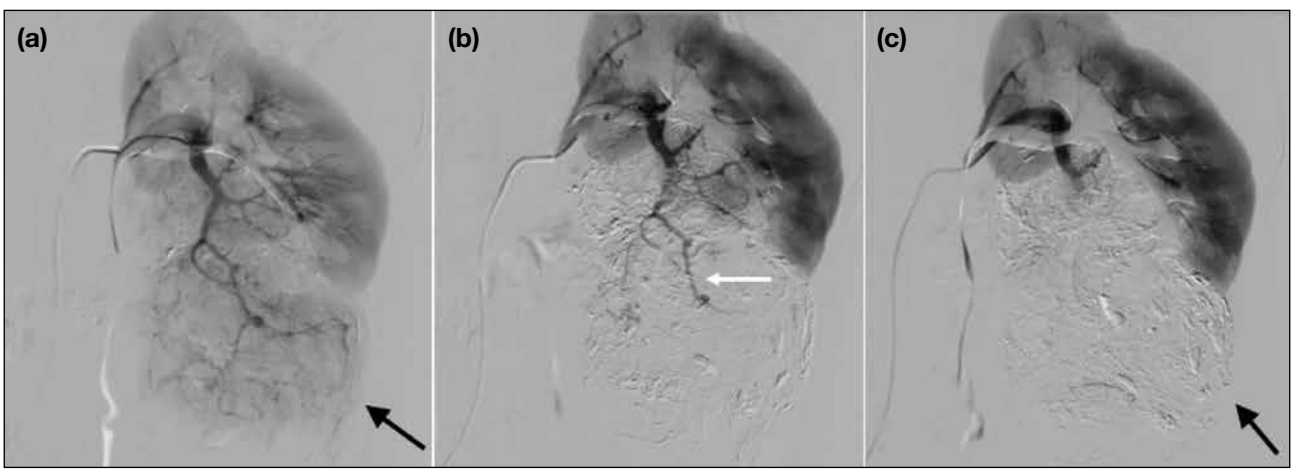

Figure 2. Arteriogram from a 37-year-old female patient with renal angiomyolipoma (AML). (a) Marked vascularity of the AML in the inferior pole of the left kidney (black arrow). (b) After the first round of embolisation, repeated angiography shows that there was still a persistent arterial feeder (white arrow) supplying the AML, indicating technical non-success. (c) After repeated embolisation with the ethanol-Lipiodol mixture, angiography demonstrates complete non-opacification of the AML (black arrow), indicating technical success.

All the cases (100%) were technically successful, which was greater than the suggested threshold of 90% according to the SIR reporting standards.[15] A paired *t* test was conducted to determine the effect of TAE on each patient's serum creatinine level. The results indicated no significant difference between the creatinine level before and after TAE (mean ± SD = 63.67 ± 12.56 μmol/L vs. 64.8 ± 13.34 μmol/L; p = 0.342), suggesting no significant renal function impairment attributable to embolisation in this series.

Complications were classified as major and minor.[15] Only one patient had a major complication, with a small dissection (1.5 cm in length and 0.2 cm in thickness) at the middle part of the left renal artery identified on post-procedure angiogram (Figure 3a). A total of 4000 IU intra-arterial heparin was injected immediately. Follow-up CT showed the small dissection of the left renal artery (Figure 3b). After discussion with the urologist and in view of the small size of the dissection, conservative management was decided upon. On repeated follow-up CT 15 months after the procedure, the dissection remained static (Figure 3c). The overall major complication rate was 3.1%, which was lower than the suggested threshold of 6% according to the SIR reporting standards.[15] Four (12.5%) patients had minor complications which were all cases of post-embolisation syndrome[16] characterised by fever and pain.

Table 1. Clinical and lesion characteristics of all patients with good versus poor response to transcatheter arterial embolisation.*

	All patients (n = 32)	Good response (n = 19)	Poor response (n = 13)	p Value
Age, y	55.2 ± 10.51	54.21 ± 10.30	56.69 ± 11.30	0.533†
Sex				0.403‡
Male	7 (21.9%)	3 (15.8%)	4 (30.8%)	
Female	25 (78.1%)	16 (84.2%)	9 (69.2%)	
Tuberous sclerosis complex	2 (6.3%)	1 (5.3%)	1 (7.7%)	1.000‡
Lesion volume before embolisation, cm^3	148.45 ± 332.96	186.89 ± 427.83	92.27 ± 77.95	0.358†
Lesion volume after embolisation, cm^3	62.63 ± 147.43	65.97 ± 190.36	57.75 ± 41.80	0.857†
Mixture of ethanol-Lipiodol injected, mL	3.61 ± 4.87	4.54 ± 6.07	2.25 ± 1.58	0.130†
Predominant angiomyogenic component of lesion	10 (31.3%)	10 (52.6%)	0	0.002‡

* Data are shown as No. (%) or mean ± standard deviation, unless otherwise specified.
† Independent sample *t* test.
‡ Fisher's exact test.

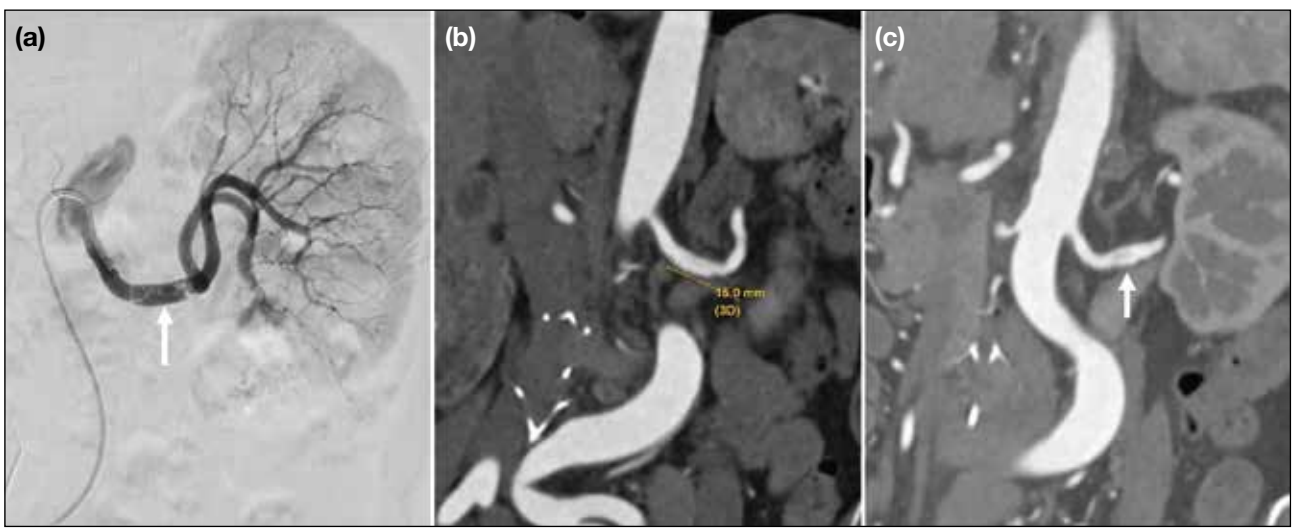

Figure 3. A 68-year-old female patient with left renal transcatheter arterial embolisation complicated by renal artery dissection. (a) Post-embolisation angiogram showing a small dissection (1.5 cm long and 0.2 cm wide) in the left main renal artery (arrow). Conservative management was decided upon. Sagittal reformat of follow-up computed tomography the next day (b) and after 15 months (c) showed that the dissection remained unchanged (arrow in [c]).

The mean hospitalisation days were 1.7 (SD = 1.6) after embolisation. Four (12.5%) patients had hospitalisations >2 days, including the day of admission to the ward before doing the procedure. Among these four patients, one case was complicated by renal artery dissection as discussed above, and three cases were complicated by post-embolisation syndrome, which responded to analgesics.

All 32 patients had follow-up CT or US with a mean imaging follow-up duration of 23.8 months (SD = 18.7). All AMLs showed reduction in volume with a mean of 59.8% (SD = 25%) observed (Figure 4). A paired *t* test indicated that there was a statistically significant difference between AML size before and after TAE (mean ± SD = 148.45 ± 332.96 cm^3 vs. 62.63 ± 147.43 cm^3; p = 0.015).

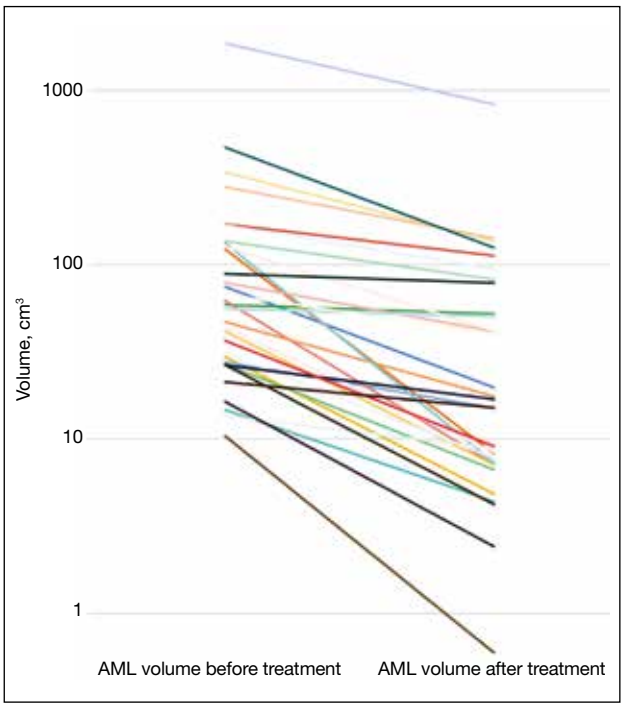

Figure 4. Angiomyolipoma volume before and after transcatheter arterial embolisation. Every single line represents each case of renal angiomyolipoma, demonstrating the volume change after embolisation.
Abbreviation: AML = angiomyolipoma.

The clinical and lesion characteristics were analysed to explore the potential association with treatment response (i.e., percentage of AML volume reduction). Table 1 summarises the clinical and lesion characteristics with good versus poor response to TAE. Statistical analysis revealed that a predominant angiomyogenic component of AML was significantly associated with good response to TAE (p = 0.002). Although the mean of pre-TAE AML volume of the good response group was greater than that of the poor response group, it did not reach statistical significance (186.89 cm^3 vs. 92.27 cm^3; p = 0.358). Similarly, the mean volume of ethanol-Lipiodol mixture injected was higher in the good response group; however, this did not reach statistical significance (4.54 mL vs. 2.25 mL; p = 0.130). There were no significant differences in patient age (p = 0.533), sex (p = 0.403), or TSC incidence (p = 1.000) [Table 1].

None of the cases required further urgent TAE for the same AML. Two (6.3%) patients had repeated elective TAE for the same AML after multidisciplinary meeting discussion. One was due to residual large size of the lesion, while the other one was due to residual large size as well as occasional flank pain suspected to be caused by intermittent bleeding despite no active contrast extravasation on serial CT. Details of the two cases are summarised in Table 2.

DISCUSSION

The study shows that TAE with an ethanol-Lipiodol mixture is effective and safe in the prophylactic treatment

Table 2. Details of two cases requiring elective repeated embolisation.

	Case 1	Case 2
Age, y	51	57
Sex	Female	Female
Indication for repeated embolisation	Suspected on-and-off bleeding; residual large size of angiomyolipoma	Residual large size of angiomyolipoma
Time of re-embolisation after the index embolisation, mo	25	19
Tuberous sclerosis complex	No	No
Lesion volume before embolisation, cm^3	172	341
Lesion volume after embolisation, cm^3	113	137
Mixture of ethanol-Lipiodol injected, mL	2.5	11
Predominant angiomyogenic component of lesion	No	Yes

of renal AML, with a high technical success rate in our centre (100%) and a low major complication rate (3.1%).

Oesterling et al[9] reported the correlation of symptoms and AML size, showing that 82% of AML with diameter >4 cm were symptomatic. Further evidence from Yamakado et al[17] supported these findings, with a lesion size >4 cm predicting the risk of rupture with a sensitivity of 100% and specificity of 38%, and an aneurysm size of 5 mm predicting the risk of rupture with a sensitivity of 100% and specificity of 86%. In our institution, we adopted these criteria (AML dimension >4 cm or pseudo-aneurysm size ≥5 mm) for prophylactic AML embolisation, and emergency embolisation for those presenting with acute haemorrhage.

Various embolic agents have been used for embolisation of AMLs, including pure ethanol, ethanol-Lipiodol mixture, polyvinyl alcohol particles, absorbable gelatin powder (Gelfoam; Pfizer Inc, New York [NY], United States), N-butyl cyanoacrylate, and coils.[18-20] In our centre, the ethanol-Lipiodol mixture is the preferred agent for embolisation. Ethanol is a potent liquid embolic agent that can cause permanent arterial thrombosis and endothelial damage resultant in necrosis of viable tissue,[21] whereas Lipiodol is iodised poppyseed oil, being radiopaque under fluoroscopy, providing better control of injection and preventing reflux.[22] The optimal ratio of the ethanol-Lipiodol mixture has been discussed in different literature, ranging from 2:1 to 4:1.[22-26] In an animal study by Gao et al[27], the effect and safety of TAE with various volume ratios of ethanol and Lipiodol in a rabbit VX2 tumour model were investigated, showing that the volume ratios of ethanol to Lipiodol from 1:2 to 4:1 were equally effective. The information gleaned from these results could provide insight to future research on the optimal ratio of ethanol-Lipiodol mixture in TAE of human renal AML. In our centre, we adopted a ratio of 2:1 ethanol to Lipiodol after balancing and optimising the therapeutic embolic effect and fluoroscopic visualisation.

The drawback of using ethanol is the potential risk of non-targeted embolisation and alcohol toxicity, which include central nervous system depression, haemolysis, and cardiac arrest. Monitoring for systemic toxicity is crucial when the dose of ethanol >1 mL/kg.[24] In our centre, we do not inject ethanol >1 mL/kg (i.e., 60 mL of ethanol for a 60 kg adult). In our study, we injected 1 mL to 26.0 mL (mean = 3.61) of 2:1 ethanol-Lipiodol mixture, which is below the limit.

The study also identified AML volume reduction percentage associated with the dominant angiomyogenic component, which was compatible with published literature.[28,29] This also correlates with the theory that ethanol causes permanent arterial damage, and hence, tumoural necrosis in the angiomyogenic component of AML, and therefore the larger the angiogenic component of the lesion, the better treatment response. This is demonstrated in Figure 5 showing pre- and post-embolisation CT, with Lipiodol predominantly staining the angiomyogenic component of the AML.

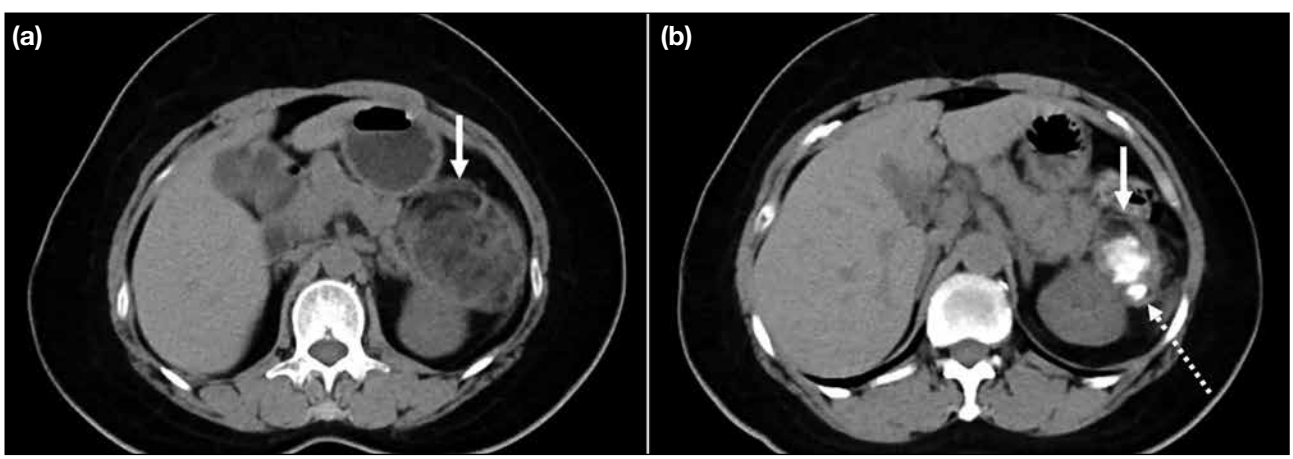

Figure 5. (a) Computed tomography (CT) of a 59-year-old woman with an exophytic fat-containing lesion (arrow) in the upper pole of the left kidney, diagnosed as renal angiomyolipoma (AML). (b) Follow-up CT of the same patient 11 months after transcatheter arterial embolisation of the AML, with Lipiodol stain (dashed arrow) in the angiomyogenic component. Note the lipomatous component (arrow) is relatively free of Lipiodol stain. There was a significant lesion size reduction, particularly of the angiomyogenic component.

Previous literature also reported initial AML volume correlates with post-embolisation volume reduction.[28] In our study, we identified that the pre-embolisation AML volume of the good response group was greater than that of the poor response group; however, it did not reach statistical significance (Table 1).

TSC-associated AML is known to develop at a younger age and tends to exhibit a much faster growth rate over time than sporadic AML. Multiple studies have demonstrated that, in contrast to sporadic AMLs, TSC-associated AMLs tend to regrow after TAE, with a recurrence rate up to 60%.[30-32] Furthermore, TSC-related AMLs tend to develop in both kidneys; therefore, medical therapy would be required. In cases of asymptomatic TSC-associated AMLs >3 cm in size, mammalian target of rapamycin inhibitors are considered as the first-line treatment.[33] However, in our study, we observed only two unilateral cases of TSC, and none of the TSC-associated AMLs required re-embolisation or showed an increase in size during the follow-up imaging at 7 months and 49 months post-embolisation, respectively. Nevertheless, further extended follow-up is necessary to conclusively ascertain the absence of AML recurrence or size escalation.

Limitations

We acknowledge this study's limitations, such as its retrospective nature and the small and heterogeneous population. The imaging follow-up periods were variable, ranging from 3 to 77 months (mean = 23.8). Also, the post-embolisation AML volume assessment was based on CT or US, which could result in measurement differences between the two imaging modalities.

CONCLUSION

TAE of renal AML using a mixture of ethanol and Lipiodol in 2:1 ratio is an effective and safe treatment option that significantly reduces the AML volume. A predominant angiomyogenic component of AML predicts significant AML volume reduction after embolisation.

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