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## Selective Arterial Embolization of Angiomyolipomas: A Comparison of Smaller and Larger Embolic Agents

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**Purpose:** Selective transarterial embolization for renal angiomyolipomas is effective in preventing or limiting hemorrhage and preserving normal parenchyma. Data are insufficient regarding the safety and efficacy of embolic agents. We compared transarterial embolization of angiomyolipomas using embolic agents of different sizes.

**Materials and Methods:** We performed a retrospective review of all transarterial angiomyolipoma embolizations from 1999 to 2010, and evaluated demographics, procedural data, embolization response and outcomes comparing smaller (less than 150 microns) and larger (more than 150 microns) embolic agents.

**Results:** Overall 48 patients underwent 66 embolization procedures for 72 angiomyolipomas. Smaller agents were used more commonly (58%). Age, gender, indications, pre-embolization angiomyolipoma size and prevalence of tuberous sclerosis were similar between the groups. Angiomyolipomas decreased a mean  $\pm$  SD 25%  $\pm$  18% after embolization with no differences between the groups ( $p = 0.24$ ). There were 10 angiomyolipomas that required 14 repeat embolizations (median 14 months). Repeat embolization of the same mass was almost sixfold more likely in those embolized with smaller agents (OR 5.88, 95% CI 1.64–20.8,  $p = 0.002$ ). Complications were similar between the groups, although 2 of 3 patients with acute respiratory distress underwent embolization with smaller agents. Patients with tuberous sclerosis had similar angiomyolipoma size, decrease in angiomyolipoma size, followup, complications and need for repeat embolization. Practice patterns changed regarding embolization agent size during the study period.

**Conclusions:** Angioembolization with larger embolic agents is associated with higher long-term efficacy compared to smaller agents. Due to concerns for serious pulmonary complications, we no longer use agents smaller than 150 microns. Prospective studies are necessary to evaluate the optimal embolization technique to achieve durable outcomes without increasing patient morbidity.

### Abbreviations and Acronyms

AML = angiomyolipoma

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\* Nothing to disclose.

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**Key Words:** angiomyolipoma; tuberous sclerosis; embolization, therapeutic; postoperative complications

ANGIOMYOLIPOMAS are hamartomas composed of muscle, fat and blood vessels which appear sporadically or as part of the tuberous sclerosis complex.<sup>1</sup> Although AMLs are benign, the risk of spontaneous hemorrhage is believed to increase with

masses larger than 4 cm.<sup>2</sup> Thus, contemporary indications for intervention include acute hemorrhage, pain or asymptomatic size greater than 4 cm.<sup>1</sup>

Preserving renal function is important in the management of AMLs, es-

pecially in patients with tuberous sclerosis complex as they are susceptible to the development of multiple and recurrent masses.<sup>3</sup> Selective arterial embolization has become the first line intervention because it is less invasive than traditional surgical approaches and enables targeted treatment of bleeding vessels.<sup>4,5</sup> Many embolic materials and sizes have been used for renal angioembolization procedures. Some investigators have proposed the use of smaller embolic agents to theoretically target smaller vessels within the tumor and potentially spare normal renal parenchyma.<sup>6–9</sup> However, smaller embolic agents may be more easily shunted into the systemic venous circulation. This is a particular concern for tumor vessels that can form arteriovenous shunts, which may or may not be angiographically evident.<sup>10</sup>

At our institution we regularly perform selective arterial embolization of AMLs. We serve as a primary referral center for many regional patients with tuberous sclerosis. We evaluated embolization agents of different sizes in the selective transarterial embolization of AMLs in a contemporary group of patients presenting to a tertiary care center.

## MATERIALS AND METHODS

We performed a retrospective review of all AML angioembolization cases performed at the University of California, San Francisco Medical Center and San Francisco General Hospital from 1999 to 2010. We identified and reviewed 48 patients who underwent 66 embolization procedures for 72 AMLs. The diagnosis of AML was made on characteristic cross-sectional imaging features such as macroscopic fat within the lesions.

Complications were categorized as major and minor, with major complications including acute respiratory distress, renal abscess requiring nephrectomy and femoral arterial injury. Minor complications included postoperative pain (intravenous pain medication, prolonged hospitalization specifically for pain control and/or continued use of oral narcotics at followup appointments), retroperitoneal hematoma not requiring transfusion and post-embolization syndrome (low grade fever, increased white blood cell count and malaise). Indications for repeat embolization included pain, hemorrhage, persistent size greater than 4 cm or subsequent increase in the size of the mass. Subgroup analyses were performed of patients with tuberous sclerosis complex.

All selective transarterial embolizations were performed by Interventional Radiology. After ultrasound guided common femoral artery access, an aortogram was used to determine the number of renal arteries. Selective renal artery catheterization and arteriography were performed, and the specific renal artery branch(es) feeding the AML were then catheterized and embolized using trisacryl gelatin microspheres (Embosphere® or Embogold®, available in sizes from 40 to 1,200 microns) or polyvinyl alcohol (available in sizes from 45 to 1,200 microns). Adjuncts to particle embolization included coils or alcohol (3 embolizations each). Embolization agents were

dichotomized as smaller agents (those less than 150 microns) and larger agents (those larger than 150 microns). Procedures in which agents of varying sizes were used were categorized based on the smallest agent used. A post-embolization angiogram was obtained to confirm complete embolization of the feeding vessels.

Outcomes were compared using conditional logistic regression with robust standard errors. Chi-square analysis was performed for binary variables and Student's *t* test was performed for continuous variables. The Wilcoxon rank sum test was performed to compare medians. Kaplan-Meier survival estimates were performed to evaluate the need for repeat embolization due to censored followup data. All *p* values were 2-tailed with significance set at *p* < 0.05. Analyses were performed using Stata® v10. This study received institutional review board approval from the University of California, San Francisco.

## RESULTS

During the 11-year study period 48 patients were identified who underwent 66 embolization procedures of 72 AMLs. Agents smaller than 150 microns were used to embolize 42 (58%) AMLs while larger agents were used to treat 30 (42%). The agent used for embolization was selected by the practitioner. Smaller agent embolizations tended to be performed with trisacryl gelatin microspheres (71%) whereas larger agent embolizations were more commonly performed with polyvinyl alcohol (61%). Demographics, indications, AML and procedure characteristics were similar between the groups (table 1).

A wide range of AML sizes were embolized (3.5 to 32 cm). The pre-embolization tumor size was  $7.8 \pm 5.9$  cm in the group treated with smaller embolic agents vs  $8.5 \pm 4.4$  cm in the larger agent group (*p* = 0.61). There was a similar decrease in size after embolization with a  $27\% \pm 18\%$  reduction with smaller agents vs a  $20\% \pm 17\%$  decrease with larger agent embolization (*p* = 0.24) (fig. 1).

During the study period 14 repeat embolizations were performed for pain (3), hemorrhage (2), or persistent (6) or subsequent increase (3) in the size of the mass with a total of 113 person-years of followup. Despite the trend toward longer followup for patients who underwent embolization with larger agents, repeat embolization of the same mass was almost sixfold more likely in those treated with smaller agents (OR 5.88, 95% CI 1.64–20.8, *p* = 0.002) with a rate of repeat embolization of 0.25 per person-year for smaller agent embolizations and 0.04 per person-year for larger agent embolizations (*p* = 0.002) (table 1 and fig. 2).

Major postoperative complications were similar for the smaller and larger embolic agent groups (*p* = 0.45, table 2). Three patients experienced acute respiratory distress, which occurred within 2 hours of the procedure, and was characterized by an acute

**Table 1.** Demographics, embolization procedure details and followup of AMLs treated with smaller vs larger agents

	Smaller Agents		Larger Agents		p Value
<i>Demographics</i>					
No. procedures (%)	38	(68)	28	(32)	
No. pt age (%):					0.08
0–20	6	(16)	1	(4)	
20–40	11	(29)	9	(32)	
40–60	12	(32)	9	(32)	
Older than 60	9	(24)	9	(32)	
Mean ± SD age	42.3 ± 19.4		47.9 ± 16.4		0.21
No. gender (%):					0.38
M	7	(18)	3	(11)	
F	31	(82)	25	(89)	
No. tuberous sclerosis (%)	16	(42)	7	(25)	0.15
No. indications (%):					0.27
Size	8	(21)	8	(29)	
Pain	10	(26)	3	(11)	
Bleeding	17	(45)	16	(50)	
Incomplete prior ablation	3	(8)	—		
Mean ± SD sessions	1.6 ± 0.7		1.5 ± 0.7		0.33
Mean ± SD vessels embolized	1.4 ± 0.7		1.4 ± 0.9		0.76
Mean ± SD masses embolized/session	1.1 ± 0.3		1.1 ± 0.3		0.63
No. arteriovenous shunts (%)	1	(3)	2	(7)	0.41
No. aneurysm (%)	1	(3)	1	(4)	0.81
<i>Embolization</i>					
No. AMLs (%)	42	(58)	30	(42)	
No. side (%):					1.0
Rt	17	(40)	12	(40)	
Lt	25	(60)	28	(60)	
No. multiple masses (%)	4	(11)	2	(7)	0.63
Mean ± SD cm pre-embolization size (range)	7.8 ± 5.9 (3.5–32)		8.5 ± 4.4 (3.5–20)		0.61
Mean ± SD cm post-embolization size (range)	6.3 ± 5.4 (2.3–26)		5.9 ± 3.1 (1.4–14)		0.81
Mean ± SD % decrease in size	27 ± 18		20 ± 17		0.24
Mean ± SD days length of stay	1.8 ± 1.2		1.5 ± 1.0		0.30
<i>Re-Embolization</i>					
No. repeat embolizations	11		3		
Person-yr at risk	43		69		
Repeat embolization/person-yr	0.25		0.04		0.002
OR, 95% CI risk of repeat embolization*	5.88 (1.64–20.8)		Reference		0.002
Mos followup:					
Mean ± SD	14 ± 16		29 ± 43		0.08
Median (IQR)	12 (0–24)		7 (0–47)		0.96

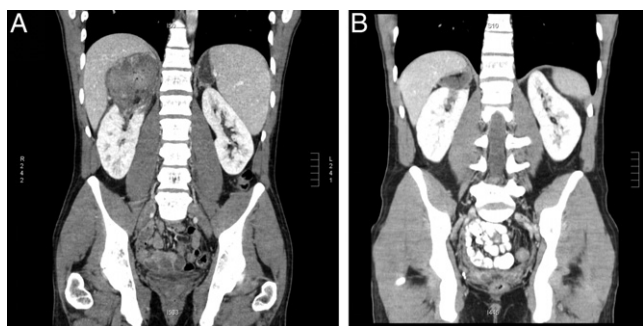
\* Using Kaplan-Meier estimates for censored followup data.

decrease in oxygen saturation requiring supplemental oxygen or endotracheal intubation. A renal abscess developed in 1 patient in the larger particle group who required nephrectomy to prevent bacterial seeding of a new mechanical aortic heart valve. Another patient treated with the larger embolic agents had a femoral artery injury at the time of the procedure requiring open surgical repair. Minor complications were also similar between the groups ( $p = 0.98$ ).

The subgroup of patients with tuberous sclerosis complex (35%) were younger ( $p < 0.001$ ), with a trend toward having multiple masses embolized ( $p = 0.15$ , table 3). Otherwise there were no differences in gender distribution, pre-embolization mass size, decrease in mass size with embolization, followup, need for repeat embolization or complications between those with and those without tuberous sclerosis complex.

When evaluated chronologically, practice patterns changed regarding embolization agent size. From 1999 through 2004, 70% of AML embolizations were performed using larger particle agents. From 2005 to midway through 2009, 80% of AML embolizations were performed using smaller agents. After 2 severe pulmonary complications occurred with smaller agents, we performed all embolizations with agents larger than 150 microns.

Exploratory analyses were performed to further evaluate the validity of this heterogeneous cohort. There were 10 patients who received a mix of agents during embolization. In these procedures patients were treated primarily with smaller agents, with larger particles (300 to 900 microns) placed at the end of embolization. Subgroup analyses revealed that the efficacy of embolization in this group was no different from that of the group that received exclu-

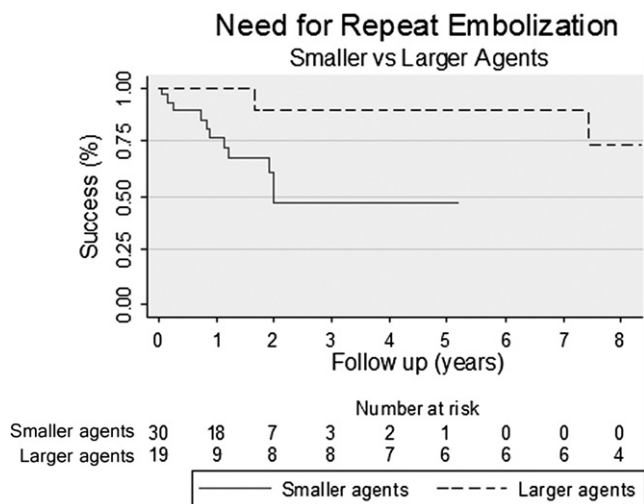


**Figure 1.** Representative coronal sections of abdominal computerized tomography with intravenous contrast demonstrating response of AML to embolization. Male patient, 26 years old, presented with symptomatic 10 cm right upper pole AML and underwent embolization with smaller than 150 micron Embospheres (A). Approximately 6 months postoperatively pain had resolved and repeat computerized tomography demonstrated decrease in size to 4 cm in greatest dimension (B).

sively smaller agents ( $p = 0.77$ ). Furthermore, the need for repeat embolization was lower in those who received exclusively larger particles than in those who received exclusively smaller agents ( $p = 0.03$ ) or mixed agents ( $p = 0.04$ ). There were no differences in complications ( $p = 0.12$ ) or the need for repeat embolization between polyvinyl alcohol and microspheres when controlling for the size of embolic agent ( $p = 0.85$ ). Coils and alcohol were used as adjuncts to embolization in 3 cases each and analyses were unchanged if these cases were excluded.

## DISCUSSION

Renal AMLs are benign masses that occur sporadically in 1% to 2% of the general population and in up



**Figure 2.** Kaplan-Meier comparison of embolization failure with need for repeat embolization of same AML comparing smaller vs larger agent embolizations.

**Table 2.** Comparison of major and minor complications for AMLs treated with smaller vs larger agents

	Smaller Agents	Larger Agents	p Value
No. major complications (%):			0.45
Acute respiratory distress	2 (5)	1 (4)	
Abscess requiring nephrectomy	—	1 (4)	
Groin arterial injury	—	1 (4)	
Totals	2 (5)	3 (11)	
No. minor complications (%):			0.98
Pain	5 (13)	3 (11)	
Bleeding	1 (3)	—	
Post-embolization syndrome	1 (3)	2 (7)	
Totals	7 (19)	5 (18)	

to 20% of patients with tuberous sclerosis complex.<sup>1</sup> The risk of life threatening hemorrhage is thought to increase for AMLs larger than 4 cm, with hemorrhage reportedly occurring in up to 51% of these masses.<sup>2</sup> Small studies have demonstrated good outcomes with observation of these masses. However, up to 60% of patients may eventually require intervention for pain or bleeding.<sup>3,11–13</sup> Minimally invasive selective targeting of small feeding arteries has made transcatheter angioembolization the new standard for AML treatment.<sup>7,14–16</sup> Nonetheless, there remains a lack of consensus with regard to the safety and efficacy of the angioembolization techniques currently used for AMLs.

We evaluated the differences in patients and outcomes between those who underwent transarterial angioembolization using agents smaller than 150 microns vs larger than 150 microns. The 150 micron threshold for smaller agents was selected based on the smallest available ranges of microsphere and polyvinyl alcohol sizes (40–120 micron Embospheres and 45–150 micron polyvinyl alcohol). A previous report regarding embolic agents of this size range raised concerns regarding nontarget distribution from liver tumor embolization.<sup>10</sup> Despite similarities in patient demographics, tumor characteristics and change in size with embolization in our study, patients who underwent embolization with smaller agents were almost 6 times more likely to require repeat embolization of the same mass (OR 5.88, 95% CI 1.64–20.8,  $p = 0.002$ ). This difference did not appear to be due to the use of coils, alcohol, agent used (polyvinyl alcohol vs microspheres) or the use of larger particles at the end of a small particle embolization. Regardless of the agent size used for embolization, AMLs decreased in size by 25% (SD 18%). This decrease is comparable to the 24% to 57% reduction in size reported in the literature using a variety of embolic agents.<sup>9,17,18</sup>

Optimal embolization agent size and material for tumor devascularization has been evaluated in animal studies. Laurent et al evaluated the distribution of

**Table 3.** Demographics, embolization procedure details and followup of patients with vs without a history of tuberous sclerosis

	Tuberous Sclerosis		No Tuberous Sclerosis		p Value
<i>Demographics</i>					
No. procedures (%)	23	(35)	43	(65)	
No. pt age (%):					<0.001
0–20	7	(30)	—		
20–40	13	(57)	7	(16)	
40–60	2	(9)	19	(44)	
Older than 60	1	(4)	17	(40)	
Mean $\pm$ SD age	28.9 $\pm$ 13.6		53.2 $\pm$ 14.5		<0.001
No. gender (%):					0.73
M	3	(13)	7	(16)	
F	20	(87)	36	(84)	
No. indications (%):					0.73
Size	7	(30)	9	(21)	
Pain	3	(13)	10	(23)	
Bleeding	11	(48)	21	(49)	
Incomplete prior ablation	1	(4)	2	(5)	
Mean $\pm$ SD sessions	1.7 $\pm$ 0.7		1.5 $\pm$ 0.7		0.22
Mean $\pm$ SD vessels embolized	1.5 $\pm$ 0.6		1.3 $\pm$ 0.8		0.47
Mean $\pm$ SD masses embolized/session	1.2 $\pm$ 0.4		1.0 $\pm$ 0.2		0.15
No. arteriovenous shunts (%)	—		3	(7)	0.08
No. aneurysm (%)	—		2	(5)	0.16
<i>Embolization</i>					
No. AMLs (%)	27	(38)	45	(63)	
No. side (%):					0.95
Rt	11	(41)	18	(40)	
Lt	16	(59)	27	(60)	
No. multiple masses (%)	4	(17)	2	(5)	0.15
Mean $\pm$ SD cm pre-embolization size (range)	9.6 $\pm$ 7.6 (4.0–31.5)		7.4 $\pm$ 3.6 (3.5–20)		0.23
Mean $\pm$ SD cm post-embolization size (range)	7.0 $\pm$ 6.6 (1.4–26)		5.7 $\pm$ 3.2 (2.3–16.8)		0.47
Mean $\pm$ SD % decrease in size	27 $\pm$ 17		23 $\pm$ 18		0.54
Mean $\pm$ SD days length of stay	1.7 $\pm$ 1.2		1.6 $\pm$ 1.1		0.86
<i>Re-Embolization</i>					
No. repeat embolizations	6		8		
Person-yrs at risk	43		70		
Repeat embolization rate/person-yr*	0.14		0.11		0.69
OR, 95% CI risk of repeat embolization*	1.23	(0.43–3.56)	Reference		0.69
Mos followup:					
Mean $\pm$ SD	20 $\pm$ 34		21 $\pm$ 30		0.86
Median (IQR)	4	(0–24)	9	(0–27)	0.46

\* Using Kaplan-Meier estimates for censored followup data.

varying sizes of trisacryl gelatin microspheres and polyvinyl alcohol particles in sheep, and reported a correlation between agent particle size and mean size of vessel occluded, with histological evidence of greater density of embolization within intratumor vessels with smaller agents.<sup>19,20</sup> However, our study demonstrated an increased need for repeat embolization in AMLs embolized with smaller agents. Larger agent embolization may provide a more proximal embolization, thus reducing the potential for angiogenesis, collateral formation and AML regrowth.

We found no difference in the need for repeat embolization in patients with tuberous sclerosis. Kothary et al evaluated 19 patients with 30 AMLs and found an overall recurrence rate of 32% with recurrences exclusively in those with tuberous sclerosis.<sup>7</sup> In our study the need for repeat embolization was left to the individual provider's discretion and it is possible that patients with tuberous sclerosis

were treated differently than those without tuberous sclerosis. To our knowledge, to date there are no studies comparing the efficacy or complications of the various embolic materials and it is unknown if there is a superior agent. Some have proposed that alcohol embolization may have a greater effect on the vascular component of the AML by permanently occluding blood flow at the capillary level distal to collateral blood flow.<sup>18</sup> Alcohols are directly toxic to the endothelium, and cause activation of the coagulation cascade and resultant tumor necrosis but may be associated with reflux of the material, embolization of other organs, pulmonary edema and/or pulmonary hypertension.<sup>21</sup>

We saw a change in practice patterns at our institution in the agents used to perform embolizations. Embolizations performed before 2005 tended to be performed with agents larger than 150 microns. In 2005 we increasingly used smaller agents for

embolization, believing that more distal embolization of smaller vessels would be more effective.<sup>6–9</sup> However, in 2009 we saw 2 patients in a 1-month period who had undergone embolization with smaller agents and experienced acute respiratory distress. After these events we transitioned entirely to agents larger than 150 microns and have had no further episodes of acute respiratory distress.

In our cohort there were 3 patients with severe pulmonary complications. A healthy 51-year-old woman had a sporadic 8.9 cm AML. She had an arteriovenous shunt within the mass during the initial arteriogram that resolved angiographically after 2 to 3 cc alcohol embolization followed by the administration of 40–120, 300–500 and 700–900 micron trisacryl gelatin microspheres. The patient had an acute oxygen desaturation to 70% requiring supplemental oxygen administration. A complete evaluation revealed new onset pulmonary hypertension.

A 78-year-old woman with tuberous sclerosis presented with acute hemorrhage of a 5.6 cm mass. She also underwent embolization using 40–120 micron trisacryl gelatin microspheres. There was no evidence of arteriovenous malformation within the AML at the time of the procedure. However, she became hypoxic with oxygen saturation in the 60% range 1 to 2 hours after the procedure and was ultimately found to have new onset pulmonary hypertension.

A 62-year-old woman with a 7.5 cm mass without angiographic evidence of an arteriovenous malformation underwent embolization using 300–500 micron polyvinyl alcohol particles. She was unable to be extubated at the end of the procedure and required endotracheal intubation for 24 hours. Chest x-ray was unremarkable. All 3 patients required prolonged supplemental oxygen during their inpatient stay while 1 patient required home supplemental oxygen for 2 weeks after the procedure.

There are emerging case reports of respiratory distress from embolization procedures. There are 5 documented cases in the literature of fatal pulmonary embolism during embolization of liver masses using 40–120 micron Embospheres, 4 of which were subsequently found to have microspheres in the ar-

terioles and alveolar walls in lung autopsy specimens. Only 1 of the 5 patients was found to have an arteriovenous shunt during the procedure, raising the concern for unrecognized vascular shunts.<sup>10,22,23</sup> Smaller embolization materials may allow the precise targeting of blood vessels. However, AMLs are composed of aberrant blood vessels that may provide a direct channel to the venous circulation, allowing access to the systemic circulation and embolization to distant sites even in the absence of appreciable arteriovenous shunting during angiography.

This study has some limitations. It is retrospective and, thus, subject to the inherent limitations of this study design. There was an institutional bias for agent size used, especially after pulmonary complications were observed and, thus, the 2 study groups had different followup durations. Complications were based on clinical presentation without access to histological proof of agent dissemination to the respiratory system. Our indications for repeat embolization may have changed during the study period. However, to our knowledge this the only study to date in the literature that specifically evaluates the complications related to embolization agent size. Randomized controlled trials are necessary to determine the appropriate agent size as well as optimal agents needed to achieve adequate treatment and shrinkage of these tumors without increasing morbidity and possible mortality.

## CONCLUSIONS

Embolization of AMLs with different embolic agent sizes results in similar reduction in tumor size. However, larger agent embolization may be less likely to necessitate repeat embolization. We found no difference in tumor size, tumor reduction size or need for repeat embolization in patients with or without tuberous sclerosis complex. Due to concerns for serious pulmonary complications with the use of smaller agents, we no longer use agents smaller than 150 microns for embolization of angiomyolipomas. Further studies are needed to more clearly define the optimal embolization technique to achieve a durable response without increasing patient morbidity.

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