


## Article

# A Multicenter, Retrospective, Matched, Comparison Study of Clinical Efficacy and Cost-Effectiveness of Caterpillar Arterial Embolization Device versus Fibered Coils in Arterial Embolization

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**Abstract:** Background: The purpose of this study was to evaluate and compare the clinical effectiveness and costs of using the Caterpillar Arterial Embolization Device (Caterpillar) and fibered coils in arterial embolization cases. Methods: In this multicenter retrospective study, demographic, laboratory, and procedural data were collected on a total of 48 patients between February 2020 and September 2020. Data were collected on 16 Caterpillar placements and matched with 32 controls who underwent coil embolization of the same vessel with a similar size. Clinical and procedural outcomes including type and size of vessels, time to vessel occlusion, fluoroscopy time, total procedure time, and costs were analyzed and compared. Results: Relative time to occlusion was significantly decreased in the Caterpillar group compared to the controls (57 ± 34 s vs. 11 min 44 s ± 8 min 13 s,  $p = 0.00001611$ ). Fluoroscopy time (6.9 ± 15 min vs. 19.2 ± 14,  $p = 0.017$ ) and total procedure time (81.0 ± 36 min vs. 111.5 ± 49 min,  $p = 0.015$ ) were significantly reduced compared to the coil group. Lastly, overall cost of embolic materials was 1050 ± 0 USD for the Caterpillar group compared to 2312.75 ± 1382.84 USD in the coil group ( $p = 0.000532$ ). Conclusion: The Caterpillar embolic devices appear safe and effective in arterial occlusion. Compared to fibered coils, the Caterpillar device results in decreased time to vessel occlusion, decreased fluoroscopy and procedural time, and decreased costs, making the Caterpillar an appealing choice for arterial embolization.

**Keywords:** embolization; vascular plug; coils; cost analysis

## 1. Introduction

Embolization is a mainstay of all interventional radiology practices with procedures encompassing the arterial and venous circulatory systems and lymphatic system [1]. The ubiquitous nature and widespread need for embolic procedures has led to great innovations in available embolic devices. Currently, there are three major types of embolic devices available: liquid, particles, and metallic devices (coils or plugs). Often, operators choose to use different embolic agents in order to achieve the desired occlusive result. These decisions are based on the anatomy, pathology, and accessibility of the lesion, as well as operator ability and preference [2]. Metallic embolic devices such as coils, Amplatzer vascular plugs (AVPs), microvascular plugs (MVPs), and Caterpillars have been used in a wide range of embolization procedures [1,3–10]. When selective embolization is required, metallic

devices such as coils and plugs are often used due to these devices being controllable to achieve precise deployment and rapid occlusion of the target vessel [5].

Coils are the oldest and most commonly used metallic embolic materials. Coils come in multiple configurations and are widely available and relatively inexpensive [7]. However, multiple coils are often needed to achieve complete occlusion, necessitating a relatively long-segment landing zone, increased costs, procedure time, and radiation dose [7,9,11]. In multiple studies of pulmonary arteriovenous malformations (PAVMs), the use of coils alone was not sufficient and caused a higher rate of both PAVM persistence, re-perfusion, and recanalization of the treated vessel compared to an AVP, often requiring repeat interventions [8–10,12]. Several risk factors for recanalization of a PAVM when using coils are proximal coil placement, oversizing, and using too few coils. This suggests that the choice of embolic device can be a significant factor in determining overall procedure success [11].

The AVP was first developed in order to address many of the issues with coils. The AVP was designed to reduce the number of required embolic devices; a single AVP can replace multiple coils, decreasing procedure and radiation time, as well as associated costs, while achieving better control in high-flow vessels [1,5]. However, the device is stiff and requires a minimum catheter size of 4Fr for deployment [2]. This significantly limits its utility in distal and small vessels. In addition, the time to complete occlusion for both coils and AVPs can be a limiting factor. Multiple studies reported occlusion times ranging from 1 to 20 min, with thrombosis occurring gradually over time [6,11]. The MVP consists of a detachable and re-sheathable soft nitinol skeleton with a PTFE coating. It is deployed through a microcatheter. This allows for precise and near-immediate embolization of extremely tortuous or small vessels and addresses some of the shortcomings of an AVP without sacrificing functionality [7]. Using an MVP limits both the number of “judgement calls” in deciding the size, number, and packing density of the coils [11]. However, the MVP itself does have several disadvantages as it requires precise sizing, a straight landing zone, and suboptimal radio-opacities [2]. Under-sizing of the device is particularly dangerous as it can lead to partial occlusion of the vessel, as well as increased risk of device migration [5].

Compared to coils or other plugs, the Caterpillar Arterial Embolization (Caterpillar) device is a newer metallic embolic device, composed of two sets of opposing nitinol fibers for stability and thrombosis with a proximal polyurethane and polyethylene occlusion membrane for rapid occlusion [1]. Initial experience with the Caterpillar device suggests an advantage in terms of improved flexibility, deployment accuracy, and rapid occlusion [1]. However, these characteristics of Caterpillar devices have not been fully investigated, and, to date, there has not been a study comparing the Caterpillar device to other metallic embolic, nor are there any studies featuring a cost analysis comparing the two device types.

The purpose of this retrospective, matched study is to compare the technical success, clinical efficacy, safety (including complication rate), procedure time, and cost of the Caterpillar device and fibered endovascular coils in various arterial embolization procedures. Our primary hypothesis is to prove that the Caterpillar device can occlude the target arteries faster than coils.

## 2. Materials and Methods

### 2.1. Patient Selection and Demographic Information

This retrospective study was approved by the institutional review board (IRB#21-000278). Data were collected from three academic hospitals. Medical records for 48 patients including demographic, medical, and procedural information between February 2020 and September 2020 were obtained: 16 Caterpillar and 32 fibered coil deployments were 1:2 matched for embolized vessel type and size. For each Caterpillar device deployed, two patients who underwent coil embolization of the same vessel with a similar size (within 1 mm as measured intra-procedurally) were selected to serve as controls. Additional information was acquired on the procedure type, time to vessel occlusion, vessel size, fluoroscopy time, procedure time, and cost. All data were statistically analyzed.

## 2.2. Laboratory Assessment

We obtained pre-procedure values for international normalized ratio (INR) and platelet counts when available in the electronic medical record. The data were analyzed for the overall dataset, as well as in two subgroups: for the Caterpillar device group and for the matched coil-embolized control group.

## 2.3. Technical Aspects

Data were collected on several technical factors for each procedure. The time to occlusion was calculated for each device by analyzing the saved images from each case. The time of the first appearance of the embolic device on the images was recorded and compared with the final post-occlusion angiographic run. These times were subtracted in order to determine the time between the deployment of the embolic device and the time until the vessel was satisfactorily occluded, termed "time to occlusion". Fluoroscopic time was chosen as a surrogate for radiation dose; it was measured in minutes and obtained from the dose reports for each case. The total procedure time was recorded by our IR technologists at the time of initial needle access time to the completion of the case in the procedure report.

## 2.4. Statistical Analysis

Continuous variables were reported as the mean  $\pm$  standard deviation. The Student's *t*-test was used to compare the differences in continuous variables. *p*-Values  $<0.05$  were regarded as statistically significant. All statistical analyses were performed using SPSS software version 22.0 (SPSS, Chicago, IL, USA).

## 3. Results

### 3.1. Patient Demographics

The study population consisted of 48 patients: 35 males and 13 females, ranging in age from 34–88 years (mean  $\pm$  SD 62.2  $\pm$  15 years) (Table 1). During the study period, 16 Caterpillar devices were deployed (Figure 1A,B), and two matched controls with coil deployment (Figure 1C,D) were obtained for each Caterpillar device deployed. These two groups were not significantly different in age. Various vessels were embolized, including the gastroduodenal artery (GDA,  $n = 24$ ), splenic artery ( $n = 9$ ), mesenteric artery branches ( $n = 9$ ), and internal iliac artery branches ( $n = 6$ ).

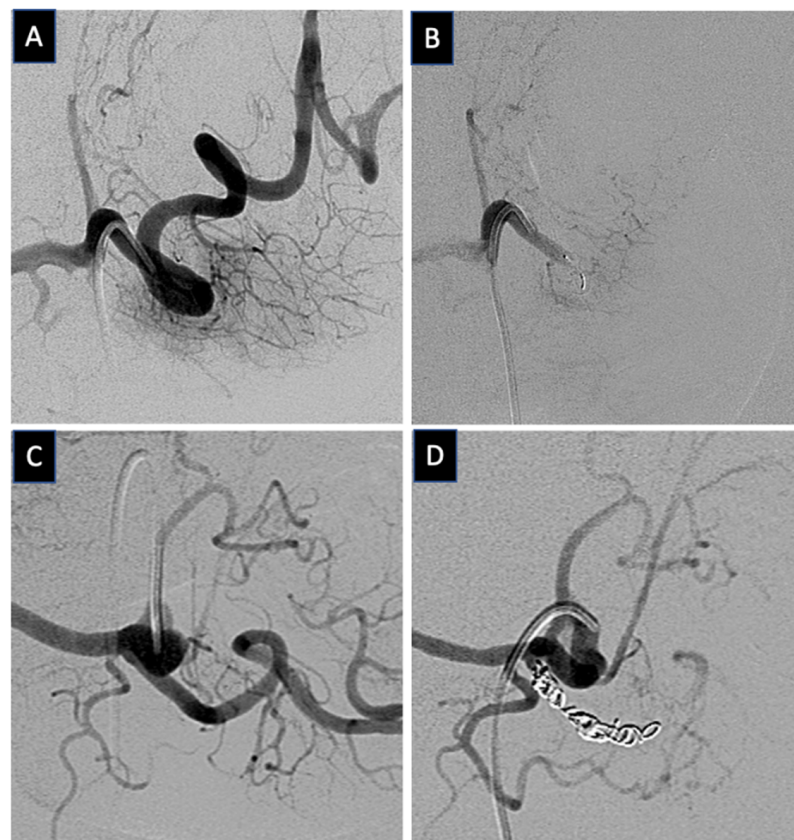
**Table 1.** Patient demographics and baseline clinical characteristics of the procedures.

	Caterpillars ( $n = 16$ )	Fibered Coils ( $n = 32$ )	<i>p</i> -Value
Age (years)	64 $\pm$ 13	58 $\pm$ 15	0.063
Sex (male), <i>N</i> (%)	13 (81.2)	22 (68.8)	0.625
Platelet count	155.3 $\pm$ 95	130.4 $\pm$ 89	0.393
INR	1.22 $\pm$ 0.2	1.33 $\pm$ 0.5	0.410
Procedures performed			
Y90 mapping	7 (43.7)	16 (50.0)	0.786
GI bleeding	4 (25.0)	6 (18.75)	0.822
Pre-op splenic embo	3 (18.8)	6 (18.75)	0.999
Pelvic trauma	2 (12.5)	4 (12.5)	1.000
Embolitic materials used			
Caterpillar Micro Arterial Embolization Device	8		
Caterpillar Arterial Embolization Device	8		
Interlock coils		32	
Concerto coils		4	
Tornado coils		4	
Average number of embolic materials used	1.0 $\pm$ 0.0	5.2 $\pm$ 2.0	0.0001

Table 1. Cont.

	Caterpillars ( <i>n</i> = 16)	Fibered Coils ( <i>n</i> = 32)	<i>p</i> -Value
Arteries embolized			
Gastroduodenal	8	16	1.000
Splenic	3	6	1.000
Mesenteric branches	3	6	1.000
Internal iliac branches	2	4	1.000
Size of arteries			
Overall (mm)	3.2 ± 1.0	3.2 ± 1.0	1.000
>2 mm	10 (62.5)	20 (62.5)	1.000
<2 mm	6 (37.5)	12 (37.5)	1.000

Data are presented as the mean ± SD as appropriate. INR = international normalized ratio; GI = gastrointestinal; op = operative.



**Figure 1.** Selective angiographic images during the splenic artery embolization procedures: (A) pre-embolization and (B) post-embolization angiogram using Caterpillar Arterial Embolization Device; (C) pre-embolization and (D) post-embolization angiogram using fibered embolization coils.

### 3.2. Laboratory Assessment

Pre-procedure laboratory values were collected on all patients (Table 1). In the study population, the mean ± SD platelet count was  $138.7 \pm 91 \times 10^3$  platelets/ $\mu\text{L}$  among all patients. Platelet count was  $155.3 \pm 95 \times 10^3$  platelets/ $\mu\text{L}$  for the Caterpillar group and  $130.4 \pm 89 \times 10^3$  platelets/ $\mu\text{L}$  for the coil group. These values were not significantly different from one another ( $p = 0.39$ ). INR values were also collected. For the entire cohort, the mean ± SD INR was  $1.30 \pm 0.4$ . In the Caterpillar group, the mean ± SD INR was  $1.22 \pm 0.2$ , while it was  $1.33 \pm 0.5$  for the coil group. These values were not significantly different from one another ( $p = 0.41$ ).

### 3.3. Time to Occlusion

The relative time to occlusion (RTO) for each vessel was calculated by subtracting the time of the initial device deployment from the time of the post-embolization angiography to confirm complete occlusion of the target vessel (Table 2). For the Caterpillar group, the mean  $\pm$  SD RTO was  $57 \pm 34$  s. In contrast, the mean RTO for the coil groups was 11 min 44 s  $\pm$  8 min 13 s for matched sized vessels. The RTO was significantly shorter in the Caterpillar group compared to the coil group ( $p = 0.00001611$ ).

**Table 2.** Comparison of embolization outcomes.

	Caterpillars ( <i>n</i> = 16)	Fibered Coils ( <i>n</i> = 32)	<i>p</i> -Value
<b>Relative time to occlusion (RTO)</b>			
Overall RTO	0 min 57 s $\pm$ 0 min 34 s	11 min 44 s $\pm$ 8 min 13 s	<b>0.000016</b>
RTO for >2 mm	0 min 50 s $\pm$ 0 min 34 s	12 min 54 s $\pm$ 8 min 46 s	<b>0.000011</b>
RTO for <2 mm	1 min 16 s $\pm$ 0 min 29 s	9 min 49 s $\pm$ 7 min 09 s	<b>0.000825</b>
<b>Embolization related time</b>			
Radiation time	19.2 $\pm$ 14 min	30.7 $\pm$ 15 min	<b>0.017</b>
Procedure time	81.0 $\pm$ 36 min	111.5 $\pm$ 49 min	<b>0.015</b>
<b>Embolic material cost in USD</b>			
Overall	1050 $\pm$ 0	2312.75 $\pm$ 1382.84	<b>0.000532</b>
Arteries >2 mm	1050 $\pm$ 0	2622.64 $\pm$ 1446.52	<b>0.000601</b>
Arteries <2 mm	1050 $\pm$ 0	1442.25 $\pm$ 721.67	<b>0.001</b>

Data are presented as the mean  $\pm$  SD as appropriate.

The RTO was analyzed in subgroups. The larger vessel subgroup (>2 mm) RTO for the Caterpillar group was  $50 \pm 34$  s compared to 12 min 54 s  $\pm$  8 min 46 s in the coil group, which was statistically different ( $p = 0.000011$ ). When analyzing the smaller vessel subgroup (<2 mm), the RTO for the Caterpillar group was 1 min 16 s  $\pm$  29 s compared to 9 min 49 s  $\pm$  7 min 9 s in the coil group, which was also statistically different ( $p = 0.001$ ).

### 3.4. Radiation and Procedure Time

Fluoroscopy time was chosen as a surrogate for the relative radiation dose (Table 2). The Caterpillar group had a significantly lower fluoroscopy mean  $\pm$  SD time at  $19.2 \pm 14$  min compared to the coil group ( $30.7 \pm 15$  min,  $p = 0.017$ ). Procedure time was estimated by subtracting the end of procedure time by the initial needle time recorded (Table 2). The mean  $\pm$  SD procedure time for the Caterpillar group was  $81.0 \pm 36$  min, compared to the mean  $\pm$  SD procedure time for the coil group of  $111.5 \pm 49$  min. This value was significantly lower in the Caterpillar group ( $p = 0.015$ ).

### 3.5. Cost Analysis

The average embolic material cost per procedure (AEMC) was analyzed using the institutional cost for all embolic materials used in each case (Table 2). The AEMC for the Caterpillar group was  $1050 \pm 0$  USD compared to  $2312.75 \pm 1382.84$  USD in the coil group ( $p = 0.000532$ ), representing a 120% increase in cost. This cost difference was even higher in the larger vessel subgroup. AEMC in the Caterpillar group in vessels >2 mm was  $1050 \pm 0$  USD compared to  $2622.64 \pm 1446.52$  USD in the coil group ( $p = 0.000601$ ), representing a 150% increase in cost. In vessels <2 mm, the AEMC in the Caterpillar group was  $1050 \pm 0$  USD compared to  $1442.25 \pm 721.67$  USD in the coil group ( $p = 0.001$ ), representing a 43% increase in cost.



#### 4. Discussion

The ability to accurately and safely deploy an embolization device is a cornerstone of a successful embolization procedure. While many embolic agents are available, they are often limited in their ability to achieve distal control and immediate occlusion, not re-sheathable, and difficult to place in tortuous or small target vessels. The Caterpillar Arterial Embolization Device (Caterpillar) appears to address many of these limitations. The Caterpillar with its dual nitinol fibers and occlusion membrane allows for accurate placement and improves occlusion timing. However, no clinical comparison studies have been performed to evaluate their embolic efficacy. In this study, we compared the embolic effects of the Caterpillar to the fibered endovascular coils in a variety of arterial embolic procedures. Overall, the Caterpillar device demonstrated a significantly shorter relative time to occlusion, significantly decreased cost, and potentially decreased radiation and procedure time compared to the fibered coil embolization in arterial procedures.

As the primary outcome, the Caterpillar embolization procedures were found to have a significantly reduced relative time to complete vessel occlusion in all procedures compared to fibered coil embolization procedures in our matched cohort. In all procedures, the Caterpillar achieved an overall 92% reduction in occlusion time from an average of 12 min to 1 min. This was due to (1) the decrease in the number of devices (one Caterpillar per procedure compared to multiple fibered coils) required for complete vessel occlusion, and (2) the proprietary occlusive membrane that is a part of the Caterpillar. This reduction in occlusion time was further analyzed in subgroups based on the vessel size (>2 or <2 mm). In the larger vessel group (2.1 to 5.1 mm), a similar reduction in occlusion time in the Caterpillar group was observed as expected, as many coils (up to 11) were needed in some cases. Similar findings were noted in the small vessel group (1.3 to 2 mm). The average occlusion time was significantly reduced in the Caterpillar group by 84% (from 9 min 49 s in the coil group to 1 min 56 s in Caterpillar group). Even though embolizing small vessels did not require as many coils or as much procedure time, more time was still needed for occlusion compared to a single device occlusion with Caterpillar. Future studies with a larger number of procedures with various vessel sizes should be performed to confirm these findings.

Shorter vascular occlusion times also translated to decreased overall procedure times. In addition to saving procedure time and radiation dose by simply requiring fewer devices (less time to open packages and deploy coils), using fewer embolic devices reduces procedure time by decreasing the number of “judgement calls” required by the operator (for example, determining the size, number, and packing density of coils). Ref. [12] In our study, mean procedure times were significantly shorter in the Caterpillar patients ( $81.0 \pm 36$  min), compared to the mean procedure time for the control group of  $111.5 \pm 49$  min. Fluoroscopy time was chosen as the surrogate for relative radiation dose. The Caterpillar group had a significantly lower mean fluoroscopy time at  $19.2 \pm 14$  min compared to the control group at  $30.7 \pm 15$  min. Saving radiation dose for both the patient and the operator has a significant clinical impact for both parties, decreasing both deterministic and stochastic radiation effects. However, we believe that the overall procedure time or radiation time assessment is not an accurate assessment, as there are many other factors involved in increasing the procedure or radiation time such as the anatomical complexity of the target vessels for embolization, operators’ experience, additional time spent on other parts of the procedure such as additional angiograms during Y90 mapping, or multiple catheter and wire exchanges. Hence, although the embolic deployment time is somewhat related to the overall procedure and radiation time, it is not truly correlative in some cases.

Perhaps one of the most important implications of our study is cost. Overall, the embolic device cost was significantly reduced in the Caterpillar group compared to the coil group by 54%. In subgroup analysis, coil embolization in larger vessels (>2 mm) would cost 150% more than Caterpillar embolization. This significant decrease in cost allows for better utilization of resources and cost efficiency. This is a small part of cost saving as the Caterpillar group also had significant time savings in embolization, which can translate to

less room time. In summary, it is more cost-effective to use Caterpillar than fibered coils in the embolization of selective vessel sizes.

Several limitations existed for this retrospective study, which relied on electronic medical records as its primary information source. However, only objective data, such as time and laboratory values, were collected, and all information was collated by two reviewers, limiting the risk of misclassification bias. In addition, the study was limited by its small sample size (16 Caterpillars and 32 matched controls). As the use of the device becomes more widespread, this concern may be addressed in a future study with a larger cohort. Additionally, inconsistent documentation may have affected the analysis of data from three institutions. Lastly, as mentioned above, the true effects on the procedure time and radiation time are not fully reliable as they were indirectly related to vessel occlusion time. Other procedural and anatomical factors can affect the procedure and radiation time. Hence, only relative outcomes of these parameters should be considered.

In conclusion, this is the first reported study comparing the efficacy and cost-effectiveness of the Caterpillar device (or any vascular plug) to conventional coils in terms of time to occlusion, as well as radiation and procedure time. Overall, the use of the Caterpillar devices allowed for accurate placement and rapid occlusion of the target vessel in every case in which they were used. Compared to coil embolization, the Caterpillar device demonstrated a significant decrease in time to vessel occlusion, relative radiation and procedure time, and embolic device cost.

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**Institutional Review Board Statement:** The retrospective clinical study was approved by the Institutional Review Board (or Ethics Committee) of the University of California, Los Angeles (IRB#21-000278, approved on 23 March 2021).

**Informed Consent Statement:** This study received a waiver of informed consent; the UCLA IRB waived the requirement for informed consent under 45 CFR 46.116(f) for the entire study.

**Data Availability Statement:** The data presented in this study are available on request from the corresponding author. The data are not publicly available due to privacy restrictions and HIPAA compliance.

**Conflicts of Interest:** E.W.L. has received consulting and research support from BD, consulting from Boston Scientific Co., and consulting from Cook Medical; N.E. has received consulting from Boston Scientific Co.

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