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Research Article

Can Detachable Embolization Coils Decrease the Cost of Materials for Portal Vein Embolization Procedures?

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Abstract

Rationale and Objectives: Preoperative Portal Vein Embolization (PVE) can induce hypertrophy of the Future Liver Remnant (FLR) prior to partial hepatectomy for malignancy. Beyond allowing better control during embolization, detachable coils are available in longer lengths, which could decrease the number of coils needed, and thus the cost of embolization materials. However, they are more expensive. The purpose of this study was to compare the use of Detachable Coils (DC) to Conventional Coils (CC) in PVE.

Materials and Methods: We retrospectively reviewed the clinical data from patients who underwent preoperative PVE, after obtaining IRB approval. Cross-sectional imaging was performed before and after PVE to assess the FLR. Demographics, liver volumes, particles and coils used, procedure times, contrast volumes, and radiation dose metrics were compared between the two groups.

Results: The study included 14 subjects in the CC group and 5 in the DC group. The right portal vein was embolized in all subjects, and 2 in the CC group also had segment 4 embolized. There was no significant difference between the groups for demographic data, volume of particles used, number of branches embolized, liver growth parameters, procedure time, contrast dose, and radiation dose metrics. A mean of 11.9 coils was used in the CC group versus 7.4 coils in the DC group (p=0.006), with a mean cost for embolization coils of $1,014 and $5,360 (p=0.0001) respectively.

Conclusion: Significantly fewer detachable coils are needed for a successful PVE procedure compared to conventional coils, but the total coil cost is much higher.

Keywords: Portal vein embolization; Embolization coils; Cost comparison

Abbreviations

PVE: Portal Vein Embolization; FLR: Future Liver Remnant; IRB: Institutional Review Board; CC: Conventional fibered Coils; DC: Detachable fibered Coils; TELV: Total Estimated Liver Volume; sFLR: standardized FLR; RVG: Relative Volumetric Growth; DH: Degree of Hypertrophy; KGR: kinetic growth rate

Introduction

Other than liver transplantation, major hepatic resection is currently the only potentially curative therapy for patients with hepatic malignancies. Increased postoperative morbidity and mortality is associated with a liver remnant that is too small [1]. Preoperative Portal Vein Embolization (PVE) of the diseased hepatic lobe has been used to induce hypertrophy in the remaining liver. The exact mechanism is not completely understood, but is believed to be related to apoptosis of the embolized segments, causing compensatory hypertrophy in the remaining liver [1,2]. With preoperative PVE a patient, whose disease is unresectable due to a Future Liver Remnant (FLR) that is estimated to be inadequate, may be converted to an operative candidate [3].

Many techniques have been used for PVE, but in general they all target portal vein occlusion at the sinusoidal level. Embolic materials used for PVE include particles, adhesives and many types of coils. One technique utilizes small particulate embolic material for the initial sinusoidal level occlusion followed by fibered coil embolization of the main lobar portal branches to prevent recanalization [4]. Conventional embolization coils available from multiple manufacturers have been used in many applications for several decades. Recently, detachable coils have become available with the potential advantage of being able to be retrieved or repositioned, improving the precision of deployment. Delivery platforms include 0.018-inch systems designed to be deployed via microcatheters, and more recently 0.035-inch systems that are deployed via standard diagnostic angiographic catheters were introduced. The retrievable design allows detachable coils to be produced in longer lengths than conventional coils, as the risk of maldeployment of a very long coil could be easily mitigated by recapture and redeployment. Due to the longer lengths, fewer detachable coils might be required for a successful PVE procedure, compared to conventional coils.

Cost containment continues to be strongly emphasized in medical practice. One disadvantage of minimally-invasive procedures is that many of the devices used are expensive and not reusable. Modified versions of conventional devices may cost several times that of the

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original, and in particular, detachable coils are more costly than conventional coils. This higher cost has a greater impact when multiple devices are required for a single procedure. Portal vein embolization is one such procedure and thus was used as a platform for cost comparison of detachable coils with conventional coils.

Materials and Methods

Study design

This retrospective study was approved by the Institutional Review Board (IRB) for research limited to the use of health/medical records and was compliant with the Health Insurance Portability and Accountability Act. All patients gave written informed consent for the PVE procedure, but study consent was waived by the IRB. All patients underwent PVE by a single operator between July 2005 and December 2012. Initially, only 0.035-inch Conventional fibered Coils (CC) were used for these procedures, as they were all that were available. Beginning June 2011, 0.035-inch Detachable fibered Coils (DC) became available and shortly thereafter they were preferentially utilized. As the embolization materials are generally the largest part of the material costs, and since these new coils came in longer lengths, it was thought that fewer coils would be needed to complete a procedure, which could decrease the cost of the embolic materials. Other potential advantages of using fewer coils included reduced procedure time, contrast dose, and radiation exposure. Also, another benefit of these coils was that they could be removed prior to complete deployment if positioning was not acceptable. However, after a short period of time, it subjectively seemed that many coils were still being used for each procedure. Thus, their use was suspended, and a decision was made to perform this formal, IRB-approved review before continuing to use them in this application.

Embolization procedure

The basic technique employed for PVE has been described elsewhere [4], but our adaptation is summarized here. Procedures were performed under intravenous moderate procedural sedation using midazolam and fentanyl. Prophylactic intravenous antibiotics (typically levofloxacin) were administered. Access was obtained via a right intercostal approach into a right portal venous branch as peripherally as possible under fluoroscopic guidance using a 21 gauge trocar needle, 0.018-inch mandril guidewire, and stiffened transitional dilatation system. A 6 French sidearm sheath was then placed via this access and portal venography performed in PA, and occasionally oblique, projection using a flush angiographic catheter and power injector.

Portal venous branches were then selectively catheterized and embolized with particles, followed by coil embolization of the segmental portal vein branches. Particles used in the CC group included Embosphere microspheres (BioSphere Medical, Roissy, France) in three subjects, Contour particles (Boston Scientific, Natick, MA) in three subjects, and Embozene microspheres (CeloNova BioSciences, Ulm, Germany) in four; Embozene particle were used in all five of the DC subjects. Only one type of particulate embolic agent was used in each patient, except for one subject in the CC group who received Embospheres to supplement the use of Embozene microspheres, and embolization of each branch commenced with small particles and size was increased stepwise. The endpoint for particle embolization of each branch was stasis, and was the same in both groups. (Figure 1) shows the amount and types of particles used for each subject.

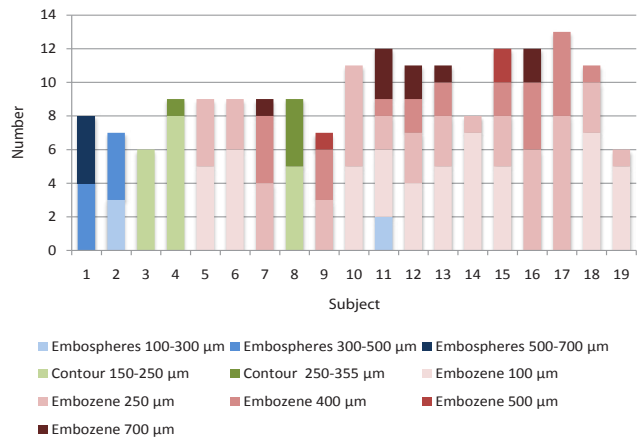

Figure 1: Amount and type of particulate embolics used per subject.

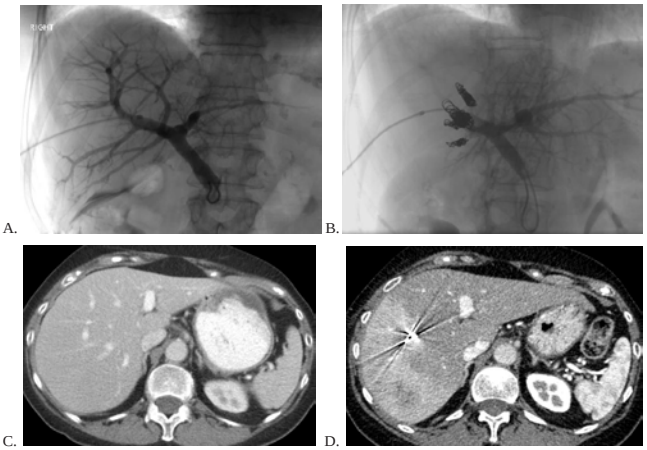

Figure 2: 73 year old female (subject #12) with metastatic colorectal cancer and left lobe sFLR of 21%. Right PVE performed with particles followed by a total of 13 conventional coils in 4 branches. Angiographic images show portal venous anatomy before (A) and after embolization (B), with flow isolated to the left lobe. Comparable field of view axial images at the level of the left portal vein before embolization (C) and 37 days after (D) show increased AP dimension of the left lobe and increased draping anterior to the stomach; left lobe DH was 22% and KGR was 4.1%/week. The patient underwent successful right hepatectomy 68 days post embolization.

After a branch was occluded with particles, coils were then placed in the branch to prevent recanalization. The endpoint was visual filling of the entire cross-section of the vessel lumen with coil material as assessed under fluoroscopy. There was not a systematic evaluation of flow after each individual coil was deployed in either group. When completeness of lumen cross-sectional filling was uncertain, coil placement erred on the side of using an additional coil, as hypertrophy failure resulting from recanalization could result in non-resectability. In the CC group, 0.035-inch 14-centimeter long Nester coils (Cook Incorporated, Bloomington, IN) were used (Figure 2) and in the DC group, 0.035-inch Interlock-35 coils (Boston Scientific Corporation, Natick, MA) were used (Figure 3). Other shorter 0.035-inch conventional coils (Tornado, Cook) and 0.018-

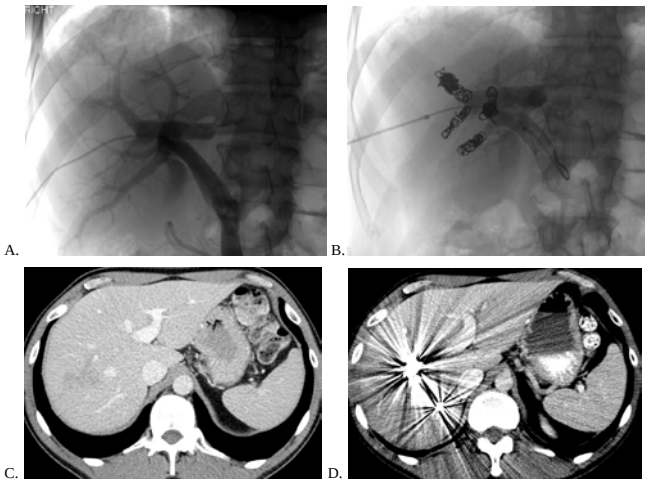

Figure 3: 40 year old male (subject #17) with metastatic colorectal cancer and left lateral lobe sFLR of 16%. Right PVE performed with particles followed by a total of 10 detachable coils in 4 branches. Angiographic images show portal venous anatomy before (A) and after embolization (B), with flow isolated to the left lobe. Comparable field of view axial images at the level of the left portal vein before embolization (C) and 27 days after (D) show straightening of the concave left lateral lobe margin; left lateral lobe DH was 8% and KGR was 2.2%/week. The patient underwent successful extended right hepatectomy with wedge resection of 4 lesions on the left 34 days post embolization.

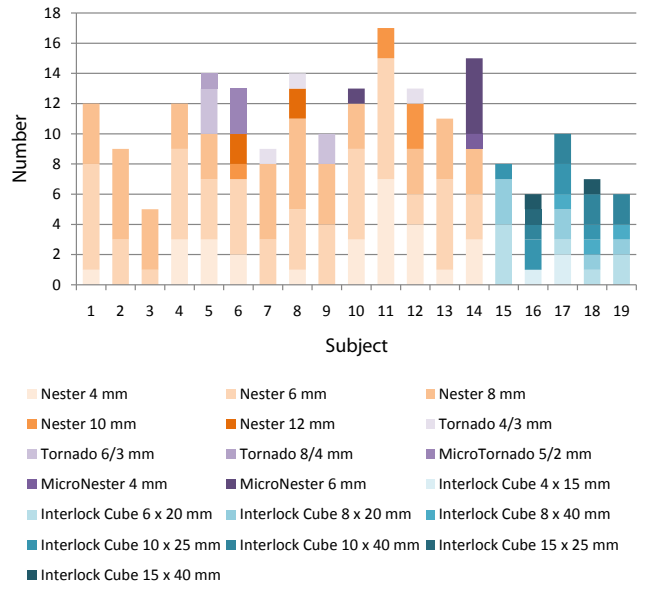

Figure 4: Number and type of coils used per subject.

inch conventional microcoils (Tornado and Micronester, Cook) were used in an adjunctive fashion as needed for small branches. (Figure 4) shows the number and types of coils used for each subject. After all branches were occluded, a completion portal venogram was performed to confirm that flow was isolated to only the left portal venous system. The sheath was then withdrawn into the entry tract, which was filled with gelatin foam slurry. Patients were observed for 6 hours prior to same-day discharge.

Cross-Sectional imaging

Total Estimated Liver Volume (TELV) was calculated, based on recent patient height and weight recorded in the electronic medical record, as previously described [5]. Pre-embolization imaging utilized recent existing CT or MR of the liver, and hepatic volumes were analyzed with 3D software (VitreaCore, version 6.6, Vital Images Incorporated, Minnetonka, MN). Post-embolization imaging was obtained approximately 5 weeks after the embolization procedure and hepatic volumes were again similarly analyzed.

Growth parameters

Calculated growth parameters included:

a) Standardized FLR (sFLR)**:** the size of the FLR relative to the TELV, defined as the pre- or post-embolization FLR, divided by the TELV. Generally, a sFLR of 25% is desired for non-cirrhotic patients and 40% is desired for those with a history of cirrhosis [6].

b) Relative Volumetric Growth (RVG): the percentage growth of the FLR with respect to its initial size, defined as the difference between post-embolization FLR and pre-embolization FLR, divided by the pre-embolization FLR.

c) Degree of Hypertrophy (DH): the change in size of the sFLR, defined as the difference between the post-embolization sFLR and the pre-embolization sFLR. A DH of more than 5% is desired for those with a normal liver and more than 10% for those with chronic liver disease [7,8].

d) Kinetic Growth Rate (KGR): the rate of growth of the sFLR, defined as DH divided by the time elapsed between PVE and post-embolization cross-sectional imaging in weeks. A KGR greater than 2% per week is desired [9].

Statistical analysis

Continuous variables were compared using a paired t-test and categorical variables were compared with a two-tailed Fisher's exact test (QuickCalcs, GraphPad Software, La Jolla, CA). A p-value of less than 0.05 was considered statistically significant.

Results

Nineteen portal vein embolization procedures were performed in the study period. Fourteen subjects (ten male) were in the CC group and five (three male) were in the DC group; gender ratio was not significantly different between the two groups (p=1.00). The mean age at the time of the PVE procedure was higher in the CC group (61.8±8.9 years versus 51.2±12.4), but it did not reach statistical significance (p=0.05). There were nine subjects in the CC group and all five in the DC group with colorectal carcinoma. Other diagnoses in the CC group included two with hepatocellular carcinoma and one each with cholangiocarcinoma, carcinoid, and sarcoma. Mean calculated TELV was very similar in the two groups (1709±217 cm3 in the CC group and 1700±345 cm3 in the DC group, p=0.95). The median time from the PVE procedure to the post-embolization imaging was 37 days in the CC group and 35 days in the DC group.

All patients underwent technically successful right PVE (segments 5-8) procedures, and 2 subjects in the CC group also had segment 4 embolized. Procedural details are given in (Table 1). There was no significant difference in number of branches embolized, total particles used, coils per branch, sedation time (as a surrogate for procedure time), contrast usage, fluoroscopy time, reference point air kerma,

Table 1: Embolization Procedure Details, mean (standard deviation).

	Conventional Coils (n=14)	Detatchable Coils (n=5)	p-value
Embolization Metrics			
Branches Embolized	4.4 (1.4)	3.4 (0.5)	0.14
Total Particles (ml)	9.0 (1.8)	10.8 (2.8)	0.11
Total Coils	11.9 (3.0)	7.4 (1.7)	0.006
Coils Per Branch	2.93 (0.93)	2.18 (0.38)	0.1
Total Coil Cost	$1,014 ($255)	$5,360 ($1,018)	0.0001
General Procedure Metrics			
Sedation Time (min)	217 (56)	231 (52)	0.63
Contrast Used (ml)	293 (64)	235 (69)	0.11
Patient Radiation Dose Metrics			
Fluoroscopy Time (min)	53.4 (22.4)	54.1 (10.9)	0.95
Reference Point Air Kerma (mGy)	1658 (717)	1536 (503)	0.73
Kerma-Area Product (Gy cm^2)	252.1 (148.9)	209.7 (90.0)	0.56

Table 2: Liver Volumes and Growth Parameters, mean (standard deviation).

	Left Lobe			Left Lobe Lateral Segment		
	Conventional Coils (n=13)	Detatchable Coils (n=5)	p-value	Conventional Coils (n=7)	Detatchable Coils (n=5)	p-value
Pre-Embolization						
FLR (ml)	600 (231)	600 (196)	1	334 (112)	299 (171)	0.68
sFLR	34.9% (12.8%)	35.0% (7.7%)	0.99	19.5% (6.7%)	17.0% (8.2%)	0.57
Post-Embolization						
FLR (ml)	843 (250)	783 (179)	0.63	511 (92)	415 (201)	0.29
sFLR	49.0% (12.4%)	46.5% (7.8%)	0.68	29.7% (3.5%)	24.3% (10.3%)	0.22
Growth Parameters						
RVG	50.8% (46.4%)	36.5% (32.5%)	0.54	64.8% (48.9%)	45.8% (37.4%)	0.48
DH	14.1% (13.6%)	11.5% (8.8%)	0.7	10.2% (7.3%)	7.2% (4.7%)	0.44
KGR	2.3% (2.3%)	2.5% (2.2%)	0.87	1.7% (1.2%)	1.5% (1.0%)	0.77

FLR: Future Liver Remnant; sFLR: standardized Future Liver Remnant; RVG: Relative Volumetric Growth; DH: Degree of Hypertrophy; KGR: Kinetic Growth Rate

and kerma-area product between CC and DC groups. Between 1 and 6 adjunctive coils were used in 8 of the 14 subjects in the CC group, and those are included in the total number of coils used in the analysis, as the cost of all conventional coils was the same. No subject in the DC group received adjunctive coils. There was a significantly lower mean total number of coils used in the DC group of 7.4 (SD=1.7, range=6-10) compared to 11.9 coils (SD=3.0, range=5-17) in the CC group (p=0.006). Conversely, there was a significantly higher mean total cost for the coils in the DC group of $5,360 ± $1,018, compared to that of the CC group of $1,014 ± $225 (p=0.0001).

Mean measured pre- and post-embolization FLR hepatic volumes, left lobe (n=13) and left lobe lateral segment (n=7), and corresponding mean calculated sFLR are shown in (Table 2); left lobe and left lobe lateral segment FLR were not both measured for all subjects. There was no significant difference between the CC and DC groups both pre- and post-embolization for any of these measured and standardized volumes. Calculated mean RVG, DH and KGR are also given in (Table 2). Again, there was no significant difference between the CC and DC groups for these hypertrophy parameters.

All five subjects in the DC group and eleven of the fourteen in the CC group underwent planned surgery. Three in the CC group did not undergo surgery due to surgeon's opinion of insufficient growth on follow-up imaging study (n=2, subject #7 with left lobe DH of 13% and KGR of 2.4%/week, and subject #9 with left lobe DH of -12% and KGR of -2.6%/week) and disease progression on the follow-up imaging study (n=1, subject #2 with left lobe DH of 12% and KGR of 0.9%/week). There were 3 of 13 with left lobe DH less than 5% in the CC group, and there was 1 of 5 with left lobe DH less than 5% in the DC group. There were 4 of 13 with left lobe KGR less than 2%/week in the CC group, and 3 of 5 with left lobe KGR less than 2%/week in the DC group. Of note, all of those with DH less than 5% also had KGR less than 2%/week.

There were five adverse events recorded with two in the CC group and three in the DC group. Recorded adverse events included one each of a partially unraveled coil that was successfully retrieved, fever and chills immediately after procedure with no sequelae on overnight observation, possible vasovagal episode, vasomotor reaction with transient flushing, intolerance of moderate procedural sedation requiring a second procedure under general anesthesia to complete the embolization, and transient hypotension felt to be due to procedural sedation. Most were later in the study period and may

have been related to more attention being paid to minor adverse events in general in the IR division.

Discussion

In the current study, both the CC and DC groups were similar for baseline parameters, and there was similar hypertrophy in both groups regardless of the type of coil used. Left lobe RVG in both groups (50.8% for the CC group and 36.5% for the DC group) were comparable to recent meta-analysis which found a mean increase of 37.9% [3].

Lack of FLR hypertrophy occurs in almost 10% of patients undergoing PVE [2]. In the current study, overall there were 4 subjects (22%) who did not achieve left lobe DH of at least 5% and 7 (39%) who did not have a left lobe KGR of at least 2%/week to signify adequate hypertrophy. However, 5 of these 7 (71%) with unfavorable growth parameters had successful surgery nonetheless. Some subjects may not have had hypertrophy, as the starting FLR may have actually been adequate using strict criteria. Exploring this finding further, when comparing the 7 with unfavorable left lobe growth parameters to the other 11, there was a significantly larger pre-PVE left lobe sFLR volume in the former (42.4% versus 30.1%, p=0.02). Some subjects had a pre-PVE sFLR greater than the usual threshold criteria outlined in the Materials and Methods section because they had known disease in the FLR; they were planned for wedge resection or radiofrequency ablation of those lesions contemporaneously with hepatectomy, and the referring surgeon desired to maximize the FLR as much as possible. Also, it may be possible that patients with a large tumor compressing the right portal vein had already induced maximal left lobe hypertrophy, and thus it did not grow more.

As there was no significant difference in growth parameters between the CC and DC groups, the efficacy is similar. In the DC group 38% fewer coils were used. However, because at the time of the study the detachable coils were nearly an order of magnitude more expensive than the conventional coils, there was a cost increase of 429% in the DC group. In order for the devices to be comparably cost effective, the detachable coils would, on average, have to cost no greater than 60% more than the cost of the conventional coils. Although not significant, there were trends toward fewer branches needing to be embolized and fewer coils per branch in the DC group, but those factors did not seem to help keep the cost down due to the substantially higher average cost per coil.

Although there were no significant differences in sedation time, contrast usage, and radiation dose metrics between the groups, there were some trends that could have reached statistical significance with a larger study group. Contrast usage was slightly higher in the CC group (293 ml vs. 235 ml, p=0.11), and this trend probably relates more to the trend for having more branches that needed to be embolized in that group (4.4 vs. 3.4), as each branch needed to be evaluated pre- and post-embolization. Thus, the hypothesized advantage of DC in reducing contrast dose was probably errant. The similar fluoroscopy time in both groups (53.4 min for the CC group and 54.1 min for the DC group) suggests similar technical complexity of the procedures [10]. Additionally, similar sedation time and radiation dose metrics may signify that deployment of fewer long coils is similar to that of deployment of a greater number of short coils.

The main limitation of this study is its small size, and it is possible a larger study might demonstrate a benefit of one type of embolization coil. Successful embolizations might have been performed with fewer coils, but that would apply to subjects in both groups. Also, it is possible that particles alone would have been adequate to induce hypertrophy, but that was not investigated, and the use of coils to prevent recanalization is an integral part of this technique we have adapted from the peer-reviewed literature. The retrospective nature of this study also introduces limitations including the lack of randomization and heterogeneity of subjects. Additionally, coil deployment technical issues were not necessarily recorded if they did not result in an adverse event. Further, the DC group, being the second group, may have benefitted from technical experience gained from the preceding CC group, although as noted the sedation times and patient radiation dose metrics were similar in both groups. Finally, having a single primary operator and using specific types of coils makes the results less able to be generalized; however, it does allow for a more consistent procedural technique across subjects which would help strengthen our findings.

Conclusion

Detachable embolization coils have an advantage in portal vein embolization in that fewer are needed for a technically successful procedure. However, due to their much higher average cost, the cost of coils per procedure is about five times that of conventional coils. Since there was similar efficacy with both types of coils, the greatly increased cost makes them much less desirable from a cost-effectiveness perspective. This effect could be seen in other embolization procedures, especially those that require a large number of coils, but should be further evaluated. The quality of retrievability may clearly outweigh the increased cost, especially if only one or two coils are needed to complete a procedure. Secondary potential benefits of decreased procedure time, contrast use, and patient radiation exposure with use of fewer, longer length coils were not seen in this small study.

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