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CLINICAL INVESTIGATION

Embolization of the Gastroduodenal Artery Before Selective Internal Radiotherapy: A Prospectively Randomized Trial Comparing Standard Pushable Coils with Fibered Interlock Detachable Coils

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Abstract The purpose of this study was compare embolization of the gastroduodenal artery (GDA) using standard pushable coils with the Interlock detachable coil (IDC), a novel fibered mechanically detachable long microcoil, in patients scheduled for selective internal radiotherapy (SIRT). Fifty patients (31 male and 19 female; median age 66.6 ± 8.1 years) were prospectively randomized for embolization using either standard coils or IDCs. Procedure time, radiation dose, number of embolization devices, complications, and durability of vessel occlusion at follow-up angiography were recorded. The procedures differed significantly in time (14:32 ± 5:56 min for standard coils *vs*. 2:13 ± 1:04 min for IDCs; $p < 0.001$); radiation dose for coil deployment (2479 ± 1237 cGycm^2 for standard coils *vs*. 275 ± 268 cGycm^2 for IDCs; $p < 0.001$); and vessel occlusion (17:18 ± 6:39 min for standard coils *vs*. 11:19 ± 7:54 min for IDCs; $p = 0.002$). A mean of 6.2 ± 1.8 coils ($n = 27$) were used in the standard coil group, and 1.3 ± 0.9 coils ($p < 0.0001$) were used in the IDC group ($n = 23$) because additional pushable coils were required to achieve GDA occlusion in 4 patients. In 2 patients, the IDC could not be deployed through a Soft-VU catheter. One standard coil dislodged in the hepatic artery and was retrieved. Vessel reperfusion was noted in only 1 patient in the standard coil group. Controlled embolization of the GDA with fibered IDCs was achieved more rapidly than with pushable coils. However, vessel occlusion may not be obtained using a single device only, and the use of sharply angled guiding catheters hampered coil pushability.

Keywords Detachable fibered coil · Gastroduodenal artery · Selective internal radiationtherapy · Transarterial embolization

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Introduction

Selective internal radiotherapy (SIRT) is a promising therapy for palliation in primary and secondary liver tumors [1–5]. For this procedure protective artificial occlusion of the gastroduodenal artery (GDA) is required beforehand because extrahepatic embolization of yttrium-90 microspheres may lead to chronic nonhealing ulcers [6, 7]. This procedure is usually achieved by transfemoral deployment of vaso-occlusive pushable platinum coils through a catheter positioned in the target vessel [8, 9]. The best coil position within the GDA is as close to the main hepatic artery as possible to exclude perfusion of small pancreaticoduodenal side branches and to ensure a retrograde blood supply by way of the superior mesenteric artery to as many branches of the GDA as possible to prevent ischemic complications. Consequently, optimal coil embolization can be technically demanding, bearing the risk of coil dislocation in the hepatic artery. In such cases, the coil may need to be recovered in a complex and risky procedure, whereas failure of recovery can result in occlusion of the hepatic artery, which may result liver dysfunction and render the planned therapy difficult or even impossible [10–13].

Detachable coil systems permit controlled deployment of an embolization coil or simple retrieval of the device if it has been suboptimally positioned. The safety afforded by a

retrievable system is of particular value for neuroendovascular applications as well as in vessels that are not amenable to embolization with conventional coils. The fibered Interlock detachable coil (IDC) system (Boston Scientific Corp., Natick, MA) is a 0.018-inch coil with a retractable interlocking mechanism designed for precise placement of a highly thrombogenic coil. Thus far, reports have mostly been limited to the use of the nonfibered IDC for the treatment of cerebral aneurysms [14–16] as well as pulmonary or renal arteriovenous fistulas [17–19]. Recently, the use of the novel fibered IDC for occlusion of vascular communications in congenital heart disease has been described [20].

The purpose of this prospectively randomized study was to assess the value of fibered IDCs compared with pushable coils for occlusion of the GDA in patients scheduled for SIRT.

Materials and Methods

Fifty consecutive patients stratified for SIRT were enrolled in this single-blinded prospectively randomized trial. Patients were assigned randomly (by drawing identical sealed envelopes from a pool) to the standard coil or IDC group, and the physician performing the procedure did not have knowledge of liver vessel anatomy or extent of tumor disease before the procedure. The study was approved by The Institutional Review Board, and written informed consent was obtained from each patient.

Before the embolization procedure all patients underwent multislice thoracoabdominal computed tomography (CT) for staging with the following parameters: breath-hold scanning (CT Aquilion 16; Toshiba, Tokyo); collimation 16 × 1 mm; and slice thickness 5 mm. Images were reconstructed with effective slice thicknesses of 1.0 and 5.0 mm, exposition at 120 kV, and tube power modulation. Delay in contrast administration was defined by Sure Start software for the early arterial phase and 80s later for the venous phase. All studies were performed after injection of 90 ml nonionic contrast medium Iomeprol (Imeron 300; Altana Pharma, Constance, Germany), which was administered intravenously into an antecubital vein at a rate of 3 to 4 ml/s with an automated double-piston injector device. After termination of contrast agent administration, 40 ml saline was injected. Sagittal maximal intensity projection (MIP) reconstructions of 1 mm–axial sections were used to measure the angle of the celiac trunk outlet, whereas coronal MIPs were used to measure the diameter of the GDA.

Cannulation of the femoral artery was performed with the patient under local anesthesia and followed by placement of a 5F sheath (Introducer II; Terumo Europe, Leuven, Belgium). The celiac trunk was intubated, depending on the degree of its outlet angle, using one of the following catheters: 5F Cobra (Imager II C2; Boston Scientific, Natick, MA), Soft-VU (Sos Omni Selective; Angiodynamics, Queensbury, NY), or Sidewinder II (Cordis, Miami, FL). The GDA was intubated coaxially with a microcatheter (Microferret; Cook Europe, Bjæverskov, Denmark), and vessel occlusion was achieved either with conventional platinum-fiber microcoils (Hilal or Tornado; Cook Europe) or with long fibered Interlock mechanically detachable coils (Boston Scientific, Natick, MA). Either 5-mm (15 cm length) or 6-mm (20 cm length) IDC was used. In case of unsatisfactory position of the first loops, the IDC was retrieved and repositioned. The goal was to deploy the IDC at the most proximal part of the GDA to prevent patency of side branches originating or reopening from the most proximal part of the GDA. We waited a maximum of 10 min for the GDA to occlude; afterwards, if necessary, additional standard coils were used. In all patients, angiographic confirmation of complete vessel occlusion after coil embolization was performed.

To document the interventional procedure, the following parameters were recorded: coil deployment time (defined as the time from commencement of the embolization to time of deployment of the last coil), fluoroscopy time for coil deployment (defined as the time of fluoroscopy for the coil deployment procedure as given by the protocol generated automatically by the machine), radiation dose for coil deployment (defined as the dose area product for coil deployment as generated automatically by the machine), embolization time (defined as time from commencement of the embolization to the moment when no further blood flow of the GDA was detected), fluoroscopy time for embolization, radiation dose for the embolization time, and amount of contrast agent used during the occlusion time. In addition, coil pushability was rated on a three-point scale (1 = good; 2 = moderate; and 3 = poor) by the physician performing the procedure.

The durability of vessel occlusion was confirmed angiographically when patients returned 12.6 ± 7.0 days after embolization for the first SIRT of the left or right liver lobe. Another angiographic confirmation was performed at the time of a second SIRT of the contralateral liver lobe after 6 weeks. In addition, material costs of the embolic devices needed for successful GDA occlusion were calculated individually.

Statistical analysis was performed with SPSS suite (version 15.0; SPSS, Chicago, IL. United States). A Mann–Whitney-Test was used to compare patients embolized with standard and IDCs for differences. A p value of 0.05 was set to be the level of statistical significance.

Results

The patient population comprised 50 patients (31 men and 19 women). Colorectal liver metastases was the most commonly encountered clinical condition ($n = 18$), followed by multifocal hepatocellular carcinoma ($n = 10$) and breast cancer liver metastases ($n = 9$). There was no significant difference in patient sex and age between the 2 groups. In addition, no significant differences were found for the diameter of the GDA (3.5 ± 0.5 mm *vs.* 3.4 ± 0.7 mm, respectively) as well as the celiac trunk outlet angle ($43.9 \pm 22.6°$ *vs.* $37.5 \pm 13.3°$, respectively) for both groups. Patient characteristics are listed in Table 1. No patients were withdrawn from the study because it was treatment independent. Three patients did not receive SIRT because of an overlarge lung shunt (>20%).

The time for coil deployment was $14:32 \pm 5:56$ min for standard coils and $2:13 \pm 1:04$ min for IDCs, which was significantly faster ($p < 0.001$). Similarly, fluoroscopy time and radiation dose for coil deployment were lower in the IDC group ($1:50 \pm 0:54$ min and 275 ± 268 cGycm^2, respectively) compared with the standard coil group ($5:23 \pm 2:46$ min and 2479 ± 1237 cGycm^2, respectively; $p < 0.001$ for both). Physicians were able to control the microcatheter as well as the IDC and withdraw the coil into the catheter for repositioning whenever necessary without difficulty. Furthermore, no difficulties with the detachment system were encountered. GDA embolization was achieved within $17:18 \pm 6:39$ min with standard coils, whereas $11:19 \pm 7:54$ min were needed with IDCs ($p = 0.002$). Subsequently, fluoroscopy time and radiation dose for GDA embolization were lower in the IDC group ($3:37 \pm 1:51$ min and 1093 ± 846 cGycm^2, respectively) compared with standard coils ($5:52 \pm 2:48$ min and 3530 ± 2575 cGycm^2, respectively; $p < 0.001$ for both). The number of standard coils implanted was 6.2 (range 3 to 12 [SD 2.0]), whereas in 83.6% of cases (19 of 23) only 1 IDC was sufficient to result in GDA occlusion. The length of this single IDC within the GDA was 14 ± 2 mm. In 4 cases, the GDA was not occluded 10 min after IDC deployment; therefore, a mean of 2.5 standard coils (range 1 to 3 [SD 1.0]) needed to be implanted in addition. Furthermore, in another 5 cases, additional pushable coils were needed to occlude the most proximal proportion of the GDA to avoid small side branches to open up and gaining reperfusion of the pancreaticoduodenal vascular territory (compare Fig. 1). To achieve this, a mean of 2.6 standard coils (range 1 to 4 [SD 1.1]) needed to be implanted. In summary, a total of 1.3 ± 0.9 coils (including the IDC) were required in the IDC group for GDA occlusion, which was significantly less compared with pushable coils ($p < 0.0001$).

The amount of contrast agent used for the procedure was significantly lower in the IDC group (4.7 ± 4.7 ml) compared with the standard coil group (10.3 ± 8.2 ml; $p < 0.001$). The average cost of coils was 457€ in the IDC group compared with 555€ in the pushable coil group ($p < 0.001$). Procedural data of GDA embolization with either pushable or IDC coils are listed in Table 2.

Whenever possible, a 5F cobra catheter was used as a guiding catheter for IDC cases (an illustrative example is given in Fig. 1). This was the result of prestudy experience that the IDC was difficult to advance in sharply angled catheters, such as the Soft-VU catheter (Sos Omni Selective; Angiodynamics, Queensbury, NY). In two patients, IDC deployment was not possible: One patient presented with a steep celiac trunk outlet angle of 19°, and the other patient had a mesentericoceliac trunk. Thus, a Soft-VU catheter was needed for intubation in both cases. Because high resistance was encountered during the attempt to push the IDC through the microcatheter, the physician decided to switch to standard coils (compare Fig. 2). Nevertheless, in both cases considerable resistance was also encountered

Table 1 Patient characteristics

Characteristic	Pushable coils			Interlock coils			*p*		
	Men	Women	All	Men	Women	All	Men	Women	All
n	17	8	25	17	8	25			–
Age (mean ± SD)	68.5 ± 9.0	63.7 ± 8.4	66.4 ± 8.9	66.4 ± 7.7	67.6 ± 8.0	66.8 ± 7.6	0.437	0.508	0.907
GDA diameter (mm)									
Mean ± SD			3.5 ± 0.5			3.4 ± 0.7			0.495
Range			2.3–4.3			2.2–4.9			–
Celiac trunk outlet angle (°)									
Mean ± SD			43.9 ± 22.6			37.5 ± 13.3			0.246
Range			8–114			15–60			–
Transferred to other group			None	1	1	2			–

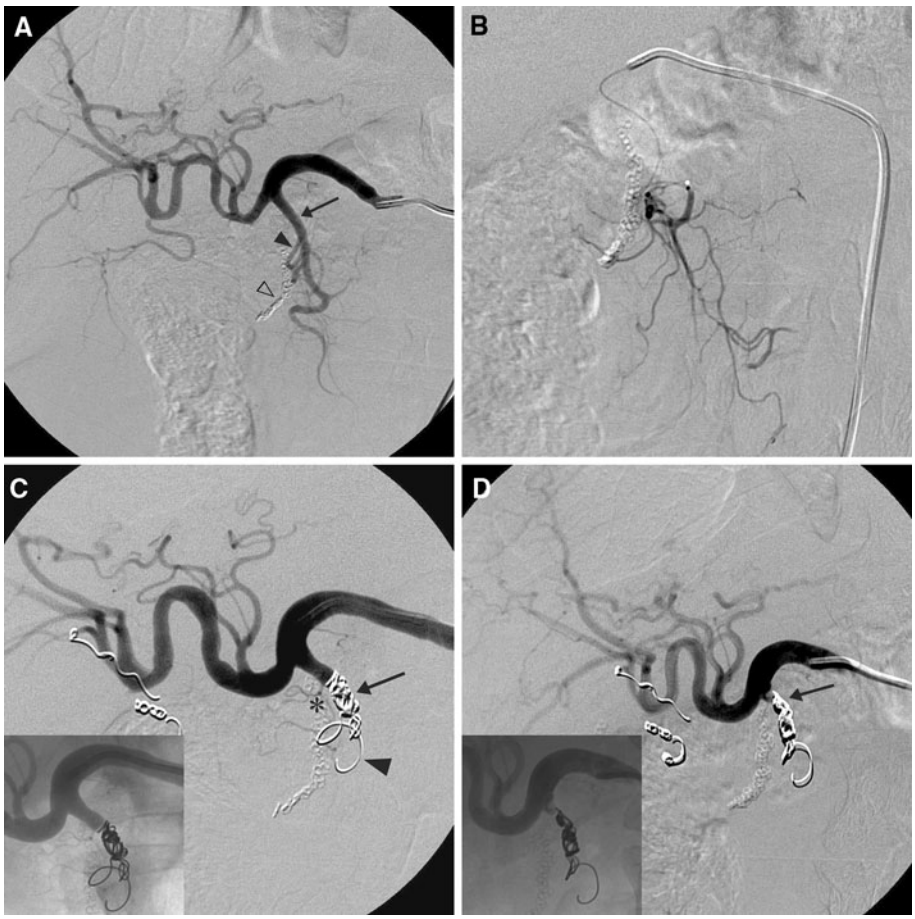

Fig. 1 (**A**) Common hepatic angiogram before protective coil embolization of extrahepatic vessels originating from the hepatic arteries in a 62-year-old male patient with hepatic metastases of rectal cancer scheduled for SIRT. The GDA (*arrow*) displays a prominent superior pancreaticoduodenal branch (*closed arrowhead*). Note radiopaque suture material from previous Billroth surgery II (*open arrowhead*). As a result, no right gastric artery, an important vessel to recognize during this procedure, could be identified. (**B**) Selective superior pancreaticoduodenal angiogram after coaxial catheterization of this side branch to use it for the coil anchor technique. (**C**) Control angiogram after coil embolization of all extrahepatic vessels. The GDA was embolized with a fibered IDC (*arrow*) with its distal part anchored in the superior pancreaticoduodenal artery (*arrowhead*). Additional standard coils were placed in the cystic artery as well as in an accessory cystic artery. Note that a small side branch has reopened to perfuse the pancreaticoduodenal vascular bed (*asterisk*). (**D**) Final angiogram shows placement of an additional 5-mm pushable fibered coil in the gastroduodenal stump (*arrow*) to ensure that no yttrium-90 microspheres were delivered to the pancreaticoduodenal area

Table 2 Gastroduodenal artery embolization with either pushable coils or ICD

Characteristic	Pushable coils	Fibered ICD	*p*
No. of coils	6.2 ± 1.8	1.3 ± 0.9	<0.0001
Coil deployment time (min)	14:32 ± 5:56	2:13 ± 1:04	<0.001
Fluoroscopy time for coil deployment (min)	5:23 ± 2:46	1:50 ± 0:54	<0.001
Radiation dose for coil deployment ($cGycm^2$)	2479 ± 1237	275 ± 268	<0.001
Time for GDA embolization (min)	17:18 ± 6:39	11:19 ± 7:54	0.002
Fluoroscopy time for GDA embolization (min)	5:52 ± 2:48	3:37 ± 1:51	<0.001
Radiation dose for GDA embolization ($cGycm^2$)	3530 ± 2575	1093 ± 846	<0.001
Amount of contrast agent (ml)	10.3 ± 8.2	4.7 ± 4.7	<0.001
Costs for coil material (€)	555 ± 177	421 ± 109	<0.001

GDA gastroduodenal artery

when using a coil pusher. In the patient with the mesentericoceliac trunk, coils could also not be deployed with a coil pusher; thus, the saline flush technique had to be used. These 2 patients were transferred to the standard coil group, but no changes in the levels of significant differences were noted. The coil pushability of IDCs was rated as

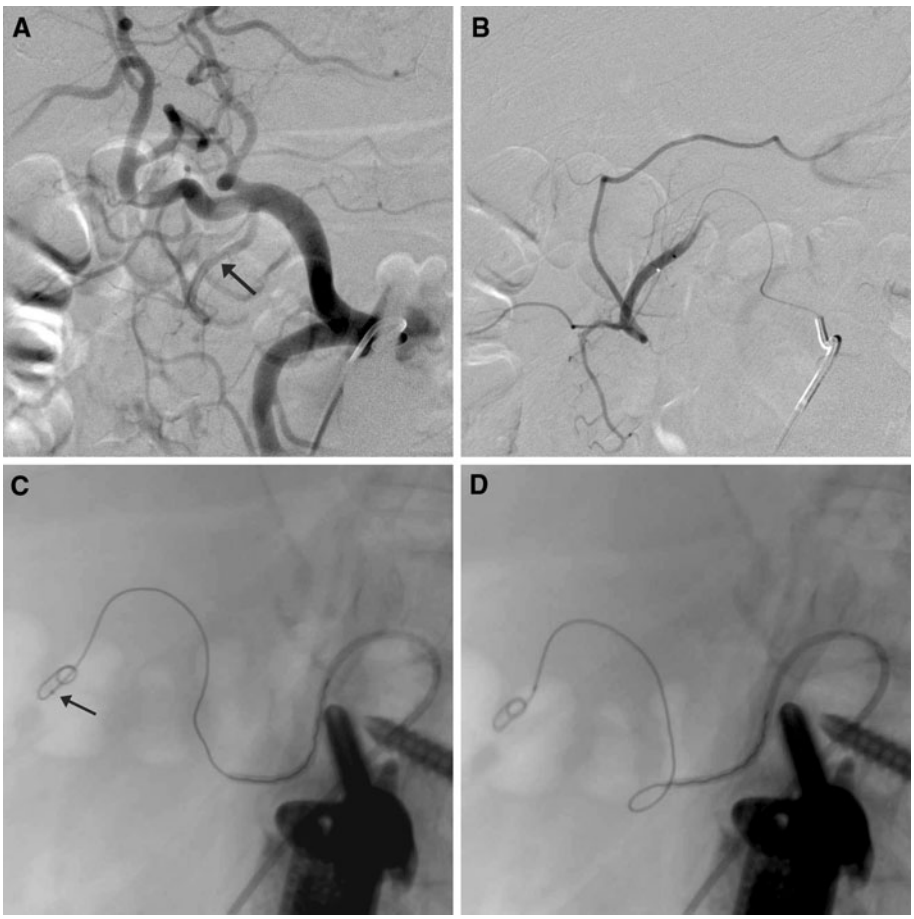

Fig. 2 (**A**) Mesentericoceliac trunk angiogram of a 61-year-old female patient with hepatic metastases of breast cancer scheduled for SIRT demonstrates the GDA (*arrow*) originating from the common hepatic artery. (**B**) Selective angiogram after coaxial catheterization of the gastroduodenal artery. Note the torsion of the Soft-VU catheter due to the course of the parent vessels. (**C**) A 5-mm IDC is advanced but only with considerable resistance. Note the deformation caused by compression of the coil within the microcatheter (*arrow*). (**D**) The microcatheter protrudes in the mesenteric artery as further force is applied (*arrow*). As a result, the IDC could not be deployed

good in 20 cases (86.7%), as moderate in 2 cases (8.7%), and as poor in 1 case, in which a Soft-VU catheter was used (4.7%). For standard coils, pushability was assessed as good in 22 cases (0.88%) and as moderate in 3 cases (0.12%). One procedural complication was encountered in the pushable coil group because one coil dislodged in the hepatic artery. It was successfully retrieved with a forceps without further complications. In contrast, no complication occurred when the IDC was used.

Technetium 99mTc albumin aggregated (99mTc-MAA) scan performed directly after embolization did not show gastroduodenal residual perfusion in any of the patients in either group. Nevertheless, reperfusion of the embolized GDA was detected at subsequent angiography (at SIRT; see Materials and Methods) in one patient who had been treated with pushable coils but in none of the patients treated with IDCs.

Discussion

The IDC is a potentially useful device with which to perform various transcatheter vascular occlusions whenever pushable coils cannot be used easily and safely. Unlike regular coils, its interlocking arms and delivery wire are meant to allow the coil to be advanced and retracted before final placement in the vessel, thus giving more control over delivery. The fibered IDC is especially appealing for peripheral applications, in which precise embolotherapy of distinct vessels or vessel pathologies must be performed.

Our results demonstrate that the use of the fibered IDC for occlusion of the GDA in patients scheduled for SIRT was safe, effective, and associated with a shorter procedure time compared with standard pushable coils, which may be of explicit benefit in patients whose general condition makes a lengthy procedure inadvisable. Precise coil placement was possible, whereas the interlocking detachment mechanism ensured a high level of control before the coil was deployed. Hence, no coil migration was encountered in the IDC group, whereas it happened once in the standard coil group. Considering only the cost of the coil material used in our study, using the IDC may save approximately €98 for each GDA occlusion. The savings can potentially be much more if operating time and labor are taken into account. In addition, the prolonged procedure time with standard coils also meant that the patients were exposed to higher radiation doses.

However, several limitations for the use of the IDC must be mentioned. First, a considerable learning curve was

necessary to perform the coil procedure as desired at the most proximal part of the GDA. We found it helpful to use the anchor technique to avoid pushing the first coil loops too deeply into the GDA, which results in a long patent proximal stump of the GDA, which requires further coil embolization (compare Fig. 1). We encountered this problem in five of the early cases. Because the fully deployed IDC has a mean length of 14 ± 2 mm, we recommend navigating the microcatheter to a side branch ideally 2 cm distal to the origin of the GDA whenever possible and subsequently using the anchor technique (compare Fig. 1). Alternatively, one may promote the scaffold technique with oversized pushable helical coils before using the IDC.

Second, the IDC cannot be regarded as being ideal in terms of reliable target vessel occlusion using only one device, although this was achieved in as much as 83.6% of cases (19 of 23). Further coils were needed in 4 cases regardless of whether the 5-mm (15-cm length) or the 6-mm device (20-cm length) was used. We hypothesize that a double vortex–shaped (dumbbell-like) coil design may be beneficial to increase the rate of vessel occlusion using only one device.

Third, the interlocking zone and the delivery wire were found to exhibit considerable rigidity, resulting in the inability to perform a controlled coiling procedure when a sharply angled guiding catheter, such as a Soft-VU catheter, was used for intubation of the celiac trunk. As a result, we tried to use a rigid Cobra catheter whenever possible. However, in two patients with demanding vascular anatomy (small celiac trunk outlet angle of 19° and common mesentericoceliac trunk), precise deployment of the IDC in the GDA was not possible (compare Fig. 2).

Fourth and last, although we did not experience a procedural complication within the study population, we encountered an authoritative incidence with the IDC in a patient with colorectal liver metastases who was scheduled for hepatic arterial infusion by implantation of an intra-arterial port. For this procedure, a softer 4F cobra catheter is routinely used, which dislodged in the common hepatic artery shortly before the IDC was fully deployed. During the attempt to retract the IDC in the microcatheter, the coil disintegrated and stretched considerably in the common hepatic artery. To prevent such an incidence in subsequent embolizations, we avoid retrieving the IDC once the coil has been deployed by more than half of its length.

In conclusion, under the procedural definitions employed in our study, the use of fibered IDCs for embolization of the GDA proved to be safe, effective, and more rapid compared with standard pushable coils. However, some limitations must be respected, and its use obliges a learning curve, as with any embolic device.

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