Overstenting the hypogastric artery during endovascular aneurysm repair with and without prior coil embolization: A comparative analysis from the ENGAGE Registry

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ABSTRACT

Background: Endovascular aneurysm repair of aortoiliac or iliac aneurysms is often performed with stent graft coverage of the origin of the hypogastric artery (HA) to ensure adequate distal seal. It is considered common practice to perform adjunctive coiling of the HA to prevent a type II endoleak. Our objective was to question the necessity of pre-emptive coiling by comparing the outcomes of HA coverage with and without prior coil embolization.

Methods: Data from the Endurant Stent Graft Natural Selection Global Postmarket Registry (ENGAGE), which prospectively enrolled 1263 endovascular aneurysm repair patients between March 2009 and April 2011 from multiple centers worldwide, were used for this study. We identified patients in whom the Endurant stent graft (Medtronic Vascular, Santa Rosa, Calif) covered one or both HAs and grouped them into cases in which prior HA embolization—coils or plugs—was performed (CE) and cases in which HA embolization was not performed (NE). The occurrence of covered HA-related endoleak and secondary interventions were compared between groups.

Results: In 197 patients, 225 HAs were covered. Ninety-one HAs were covered after coil embolization (CE group), and 134 HAs were covered without prior coil embolization (NE group). Both groups were similar at baseline and had comparable length of follow-up to last image (665.2 ± 321.7 days for CE patients; 641.6 ± 327.6 days for NE patients; $P = .464$). Importantly, both groups showed equivalent iliac morphology concerning common iliac artery proximal, mid, and distal dimensions and tortuosity, making them suitable for comparative analysis. During follow-up, HA-related endoleaks were sparse and occurred equally often in both groups (CE 5.5% vs NE 3.0%; $P = .346$). Secondary intervention to resolve an HA-related endoleak was performed twice in the CE group and three times in the NE group. Late non-HA-related endoleaks occurred more often in the CE group compared with the NE group, (25.0% vs 15.0%; $P = .080$). Secondary interventions for other reasons than HA-related endoleaks occurred in 7.5% of NE cases and 15.4% of CE cases ($P = .057$), mostly for occlusions in the ipsilateral iliac limb. During follow-up, 19 NE patients and 9 CE patients died, which is not significantly different ($P = .225$), and no deaths were related directly or indirectly to HA coverage. Also, no reports of gluteal necrosis and bowel ischemia were made.

Conclusions: This study shows that HA coverage with the Endurant endograft without prior coil embolization does not increase the incidence of endoleak or related secondary interventions. These findings together with the already available evidence suggest that omission of coil embolization may be a more resource-effective strategy whenever HA coverage is required. (J Vasc Surg 2018;67:134-41.)

Since Parodi et al first described minimally invasive endovascular techniques in 1991,[1] endovascular aneurysm repair (EVAR) has become the preferred way to treat abdominal aortic aneurysms (AAAs) whenever feasible.[2] In 40% of EVAR cases, the aneurysm extends into the iliac tract.[3,4] Involvement of the common iliac artery (CIA) poses significant challenges for EVAR because it might jeopardize distal sealing.

In many cases, extension of the endograft into the external iliac artery is chosen to reach an adequate distal sealing zone, which is considered to be approximately 10 to 15 mm in length.[3,5] This means intentional graft coverage of the hypogastric artery (HA). Exclusion of the HA by graft coverage has been proven relatively safe but implies a risk for type II endoleak.[6] To prevent these type II endoleaks, it is considered common

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practice to pre-emptively occlude the HA with coils or plugs.[7,8]

In our opinion, there is no solid evidence on the benefits of coil embolization, but it may be associated with higher costs and potential risk for pelvic ischemia.[9,10] Therefore, the necessity of this preventive strategy is questioned. In the past decade, several observational studies have compared pre-emptive embolization with simple coverage of the HA, but these studies represent only small series or cases in which attempted coil embolization had technically failed or in which the HA had been covered inadvertently.[11-18] To date, no large comparative study with sufficient follow-up exists.

The purpose of this study was to find out if the omission of coil embolization leads to an increased risk for HA-related endoleaks and reinterventions. A retrospective analysis was performed on data from the Endurant Stent Graft Natural Selection Global Postmarket Registry (ENGAGE).

ARTICLE HIGHLIGHTS

- **Type of Research:** Retrospective analysis of prospectively collected data of the Endurant Stent Graft Natural Selection Global Postmarket (ENGAGE) multicenter worldwide registry
- **Take Home Message:** Coverage of 134 hypogastric arteries (HAs) without prior coil embolization did not increase the incidence of endoleak or related secondary interventions compared with 91 cases when the HA was embolized before overstenting during endovascular aneurysm repair.
- **Recommendation:** Data suggest that omission of coil embolization during endovascular aneurysm repair is likely a more resource-effective strategy whenever HA coverage is required.

METHODS

Patient sample and group selection. The database of the ENGAGE Registry for AAA patients treated with an Endurant stent graft (Medtronic Vascular, Santa Rosa, Calif) was used for this analysis. From March 2009 to April 2011, ENGAGE prospectively enrolled 1263 patients from 79 sites in 30 countries worldwide. All patients were considered to be eligible for EVAR treatment as assessed by their own physician, including patients outside Endurant instructions for use criteria. No patients with ruptured aneurysms or hemodynamically unstable patients were enrolled. Further methodologic details of the ENGAGE Registry have been described in previous publications.[5,19]

From the ENGAGE database, we retrospectively identified patients in whom the distal ends of the device, including extensions, were placed covering one or both HAs. These patients were divided into two groups: one in which HA embolization—coils or plugs—was performed before the EVAR procedure (CE) and one in which HA embolization was not performed (NE).

Procedure. Computed tomography angiography (CTA) imaging of the abdomen and pelvis was done in each patient to determine baseline aortoiliac and aneurysmal dimensions to make a customized plan with respect to stent diameters and length. If found necessary, coil embolization or placement of an Amplatzer plug (St. Jude Medical, St. Paul, Minn) was performed before or during the initial implant procedure. In all cases, the decision of whether to coil embolize was left to the discretion of the surgeon. All procedures were performed under fluoroscopic control by experienced vascular surgeons or interventional radiologists. Anesthetics, antibiotics, and heparin were administered following local regimens. A completion angiogram was made at the end of implantation to document the initial technical outcome.

Follow-up and outcome. Follow-up was planned according to standard practice at each clinical site. If any adverse events were noticed, such as gluteal necrosis or buttock claudication, local investigators were obligated to report this. Bowel ischemia was considered a major adverse event, together with all-cause mortality, myocardial infarction, paraplegia, renal failure, respiratory failure, stroke, and procedural blood loss ≥1000 mL.

To identify technical complications, CTA scans were required at 30 days, at 1-year follow-up, and yearly thereafter (CTA or duplex colored Doppler ultrasound). The presence of an endoleak was classified by location and type and recorded. Occlusions or stenoses that required secondary interventions were also recorded. Endoleaks classified as distal type I, type II deriving from the HA, and distal type III located ipsilateral to the HA that was covered were considered to be related to covering of the HA.

Data collection, quality control, and statistical analysis. Local investigators collected data on each patient and recorded this on web-based electronic case report forms to ensure reliable data collection, data management, and secure authentication. Data managers reviewed 100% of data to detect missing or inconsistent data to generate queries to the investigators for resolution. In addition, Medtronic Bakken Research Center BV (Maastricht, The Netherlands) randomly monitored >40% of patients' source documentation against the data entered.

Statistical analysis was performed using SPSS version 21 for Mac (IBM Corp, Armonk, NY). Categorical variables are presented as frequencies with percentages. Continuous variables are presented as mean ± standard deviation. For outcomes concerning individual iliac arteries, a per covered internal iliac artery or HA analysis was

Table I. Overview of patient selection

ENGAGE population	(N = 1263)
No coverage of HA	1066 (84.4)
Coverage of one or both HAs	197 (15.6)
Coverage of left HA only	81 (41.1)
No prior coil embolization	47
Prior coil embolization	34
Coverage of right HA only	88 (44.7)
No prior coil embolization	49
Prior coil embolization	39
Coverage of both HAs	28 (14.2)
No prior coil embolization	17
Prior coil embolization of one HA	6
Prior coil embolization of both HAs	5
Per patient analysis	(n = 197)
No prior coil embolization at all	113 (57.4)
Prior coil embolization of one or both HAs	84 (42.6)
Per covered HA analysis	(n = 225)
No prior coil embolization	134 (59.6)
Prior coil embolization	91 (40.4)

ENGAGE, Endurant Stent Graft Natural Selection Global Postmarket Registry; *HA*, hypogastric artery.
Values are reported as frequencies (%).

performed. For general outcomes, a per patient analysis was done. Groups were compared for baseline differences and outcome variables using the independent samples *t*-test, Mann-Whitney *U* test, Fisher exact test, and Pearson χ^2 test where appropriate. *P* value ≤ .050 was considered statistically significant.

The registry was conducted according to the Declaration of Helsinki and the International Conference on Harmonization Good Clinical Practice guidelines. Local ethics committees at all participating sites approved data collection and analysis. Written informed consent for authorization of data release was obtained from all patients.

RESULTS

Population description. Among the 1263 ENGAGE patients, we identified 197 (15.6%) patients who had one or both HAs covered during the EVAR procedure (Table I). Unilateral coverage was performed in 169 (85.8%) cases, and bilateral coverage occurred in 28 (14.2%) cases. Therefore, a total of 225 covered HAs were at risk for HA-related complications. Coil embolization or plugging (CE) was performed in 91 (40.4%) of these, with approximately two-thirds of cases on the same day or during the EVAR procedure and one-third on average 15 days (range, 1-31 days) before the initial procedure. In all five cases of bilateral coil embolization, coiling was performed in a two-stage approach; one HA was coiled on average 7 days (range, 6-10 days) before the EVAR procedure, the other HA was coiled within the same setting. Covering of an HA without prior coil embolization or plugging (NE) occurred 134 (59.6%) times. For baseline characteristics and general outcomes, 113 (57.4%) patients who had no prior coil embolization at all were compared with 84 (42.6%) patients in whom prior coil embolization was performed in one or both of the covered HAs.

Baseline demographics and morphology. Patient demographics and risk factors are displayed in Table II. Patients in both groups were predominantly 73-year-old men, with an American Society of Anesthesiologists class 2 or class 3, who presented with an asymptomatic aneurysm. There were no differences in age, gender, American Society of Anesthesiologists classification, and risk factors between NE and CE patients. Also, AAA morphology concerning maximum AAA diameter, proximal neck length, diameter, and angulation was comparable between both groups.

Detailed morphology of the CIA ipsilateral of the covered HA is shown in Table III. There were no significant differences between the NE and CE groups. A CIA diameter of 24 mm was considered the maximum diameter for adequate sealing with the bell-bottom technique (using a 28-mm iliac limb graft with 20% oversizing).[5] Proximal CIA diameter was comparable and not larger than 24 mm in 94.1% and 89.2% of cases, respectively (*P* = .327). The distal CIA diameter was also comparable in both groups and not larger than 24 mm in 94.8% and 95.4% of cases (*P* = .344). CIA aneurysms were present in 80.3% of NE cases and 82.0% of CE cases (*P* = .749), and the mean maximal CIA aneurysm diameter was not different between both groups (34.7 ± 11.7 mm vs 36.0 ± 12.0 mm; *P* = .533). In approximately 50% of cases (53.3% NE vs 48.8% CE; *P* = .551), the nonaneurysmatic length of the CIA was <20 mm. Also, no differences were seen in the severity of tortuosity between CE and NE cases.

Early outcome comparison. All 197 patients underwent a successful EVAR procedure, with no intraoperative mortality and no immediate conversions. The distribution of type of anesthesia used was comparable in NE and CE patients, with approximately 65% of patients receiving general anesthesia. Equally, no difference was seen in intraoperative contrast agent use (NE, 149.2 ± 76.0 mL; CE, 153.4 ± 70.4 mL; *P* = .703) and perioperative blood loss (NE, 198.6 ± 165.4 mL; CE, 241.3 ± 325.2 mL; *P* = .237). However, surgery time was 23 minutes longer in CE patients (NE, 105.0 ± 44.1 minutes; CE, 128.1 ± 59.2 minutes; *P* = .002), and CE patients were significantly longer exposed to X rays (NE, 22.9 ± 13.2 minutes; CE, 26.3 ± 15.0 minutes; *P* = .001). Postoperative stay was not significantly different for NE patients (4.6 ± 3.6 days) and CE patients (5.3 ± 4.4 days; *P* = .239), and a comparable proportion of patients was

Table II. Baseline patient demographics and risk factors (per patient analysis)

Variable	NE (n = 113)	CE (n = 84)	*P* value
Age, years	73.0 ± 8.0	73.7 ± 7.8	.539
Gender			.303
Male	94.7 (107/113)	97.6 (82/84)	
Female	5.3 (6/113)	2.4 (2/84)	
ASA classification			.804
Class 1	8.8 (10/113)	4.7 (4/84)	
Class 2	40.7 (46/113)	42.9 (36/84)	
Class 3	36.3 (41/113)	42.9 (36/84)	
Class 4	14.2 (16/113)	9.5 (8/84)	
Aneurysm morphology			
Maximum AAA diameter, mm	61.2 ± 15.0	58.9 ± 11.0	.178
Proximal neck diameter, mm	24.6 ± 3.8	24.2 ± 3.5	.235
Proximal neck length, mm	27.0 ± 12.2	30.3 ± 13.1	.108
Infrarenal neck angle, degrees	33.2 ± 29.2	32.9 ± 25.5	.586
Suprarenal neck angle, degrees	23.2 ± 20.5	17.8 ± 19.4	.168
Symptoms			.189
Asymptomatic aneurysm	84.1 (95/113)	90.5 (76/84)	
Symptomatic aneurysm	15.9 (18/113)	9.5 (8/84)	
Risk factors			
Tobacco use	49.1 (53/108)	48.8 (40/82)	.968
Hypertension	69.0 (78/113)	74.4 (61/82)	.414
Hyperlipidemia	53.8 (56/104)	60.8 (48/79)	.350
Obesity[a]	59.1 (65/110)	67.5 (56/83)	.233
Diabetes	18.0 (20/111)	22.0 (18/82)	.497
Cancer	19.6 (22/112)	20.7 (17/82)	.852
Cardiac disease	52.2 (59/113)	52.4 (44/84)	.981
Pulmonary disease	23.2 (26/112)	25.3 (21/83)	.736
Renal insufficiency	17.3 (19/110)	13.1 (11/84)	.425
Cerebrovascular disease	11.5 (13/113)	13.1 (11/84)	.735
Peripheral vascular disease	33.6 (38/113)	27.4 (23/84)	.348
Gastrointestinal complications	15.9 (18/113)	17.9 (15/84)	.720

AAA, Abdominal aortic aneurysm; *ASA*, American Society of Anesthesiologists; *CE*, coil embolization or plugging; *NE*, without prior coil embolization or plugging.
Values are reported as mean ± standard deviation or frequencies (%) (n/N). Denominator differs when there are missing values.
[a]Obesity is defined as body mass index >25.

postoperatively admitted to the intensive care unit (37.2% NE vs 42.9% CE; $P = .416$).

At final angiography, minor endoleaks were seen in both groups and left untreated; unrelated endoleaks (proximal and contralateral type I and type III endoleaks, lumbar and inferior mesenteric artery type II endoleaks) were equally divided over both groups. HA-related type I, II, or III endoleaks were seen at final angiography in seven (5.2%) NE cases vs six (6.6%) CE cases ($P = .666$). One NE patient died at postimplantation day 199 from pneumosepsis with an initial type II HA endoleak still present on 30-day imaging. All other HA-related endoleaks were not seen any longer on 30-day imaging studies (Table IV).

Outcome of follow-up. Clinical follow-up of patients was comparable in both groups with a mean of 681.8 ± 299.6 days in NE patients and 701.2 ± 295.1 days in CE patients ($P = .530$), ranging from 21 to 1276 days. Also, follow-up to last image was comparable (NE, 641.6 ± 327.6 days; CE, 665.2 ± 321.7 days; $P = .464$), ranging from 6 to 1276 days. Table V specifies outcomes throughout the follow-up period.

Overall, 15.0% (17) of NE patients and 20.2% (17) of CE patients ($P = .340$) underwent secondary interventions for any reason during follow-up. Two of these were conversions to open surgery for non-HA-related endoleaks, one in each group (one CE patient with a persistent type II lumbar endoleak, already mentioned). One NE patient received an aortobi-iliac prosthesis at postimplantation day 49 because a large type IA endoleak was noted at 1-month imaging, with no possibility for placement of a proximal extension of the endoprosthesis. Endoleaks of any type occurred more often in CE patients (25% CE vs 15% NE); however, there was no statistically significant difference ($P = .080$).

During follow-up, HA-related endoleaks were scarce and occurred as frequently in CE cases (5 [5.5%]) as in NE cases (4 [3.0%]; $P = .346$; Table V). In the NE group, three type IB endoleaks presented at postimplantation days 11, 348, and 1165, respectively, and were resolved by deploying a limb extension farther into the external iliac artery. One patient (in a case already mentioned earlier) died with a distal type II endoleak still present. Among the CE cases, three distal type II endoleaks were seen at 1 month, but all resolved without intervention. A type IB and a distal type III endoleak were noticed on days 732 and 844 after implantation, respectively, and resolved by placement of an endovascular extension. Overall, HA-related secondary interventions occurred more often in CE cases (7.5% NE vs 15.4% CE; $P = .057$), predominantly for resolving occlusions or significant stenosis in the ipsilateral limb (5.2% NE vs 13.2% CE; $P = .035$). Remarkably, there was no difference between both groups in reinterventions for HA-related endoleaks (2.2% NE vs 2.2% CE; $P = .984$).

More patients died in the NE group compared with the CE group during follow-up, 16.8% (19 patients) and 10.7% (9 patients), respectively, but this difference was not significant ($P = .225$). No deaths were related directly or indirectly to HA coverage (Table V). Throughout the

Table III. Baseline common iliac artery (*CIA*) morphology (per covered hypogastric artery [HA] analysis)

Variable	NE (n = 134)	CE (n = 91)	*P* value
Proximal CIA diameter,[a] mm	15.4 ± 5.4 (5-45)	17.0 ± 5.8 (9-38)	.175
>24 mm	5.9 (6/101)	10.2 (6/59)	.327
Central CIA diameter,[a] mm	29.8 ± 13.6 (7-62)	31.1 ± 14.3 (10-85)	.156
>24 mm	72.7 (96/132)	76.4 (68/89)	.540
Distal CIA diameter,[a] mm	15.2 ± 5.2 (7-45)	15.8 ± 4.1 (8-31)	.482
>24 mm	5.2 (5/96)	4.6 (3/65)	.344
Nonaneurysmatic length of CIA,[a] mm	16.9 ± 25.5 (0-116)	23.8 ± 23.4 (0-127)	.106
<20 mm	53.3 (48/90)	48.8 (40/82)	.551
Aneurysm morphology[a]			
CIA aneurysm present	80.3 (106/132)	82.0 (73/89)	.749
Maximum CIA aneurysm diameter, mm	34.7 ± 11.7	36.0 ± 12.0	.533
Iliac tortuosity[a]			.896
Mild	47.2 (60/127)	47.7 (38/88)	
Moderate	40.9 (52/127)	40.9 (36/88)	
Severe	11.8 (15/127)	11.4 (10/88)	

CE, Coil embolization or plugging; *NE,* without prior coil embolization or plugging.
Values are reported as mean ± standard deviation (range) or frequencies (%) (n/N). Denominator differs when there are missing values.
[a]Measurements are taken from the affected iliac side only.

Table IV. Initial procedural data and evaluation (per patient analysis)

Variable	NE (n = 113)	CE (n = 84)	*P* value
Duration of implant procedure, minutes	105.0 ± 44.1	128.1 ± 59.2	.002[a]
Type of anesthesia			.858
General	64.6 (73/113)	65.5 (55/84)	
Spinal or epidural	23.0 (26/113)	20.2 (17/84)	
Local	12.4 (14/113)	14.3 (12/84)	
Volume of contrast material, mL	149.2 ± 76.0	153.4 ± 70.4	.703
Total fluoroscopy time, minutes	22.9 ± 13.2	26.3 ± 15.0	.001[a]
Perioperative blood loss, mL	198.6 ± 165.4	241.3 ± 325.2	.237
Postoperative stay, days	4.6 ± 3.6	5.3 ± 4.4	.239
Admission to ICU	37.2 (42/113)	42.9 (36/84)	.416
Evaluation			
Intraoperative mortality	0.0 (0/113)	0.0 (0/84)	—
Conversion to open surgery	0.0 (0/113)	0.0 (0/84)	—
Endoleakage at final angiography			
Type I or III endoleak	5.3 (6/113)	8.3 (7/84)	.398
Type II endoleak	11.5 (13/113)	11.9 (10/84)	.931
CHA-related type I, II, or III endoleak[b]	5.2 (7/134)[b]	6.6 (6/91)[b]	.666[b]

CE, Coil embolization or plugging; *CHA-related,* at covered hypogastric artery side; *ICU,* intensive care unit; *NE,* without prior coil embolization or plugging.
Values are reported as mean ± standard deviation or frequencies (%) (n/N). Denominator differs when there are missing values.
[a]Significantly different.
[b]Analyzed per covered internal iliac or hypogastric artery.

follow-up period, no instance of bowel ischemia was reported. Also, gluteal skin necrosis was not mentioned in any of the reported adverse events. Furthermore, a total of 16 reports on adverse events mentioned symptoms of claudication, but none of these specified buttock claudication. There was an equal distribution of cases between NE patients and CE patients, 8.0% (nine) vs 8.3% (seven), respectively ($P = .925$). Notably, in both groups, there were patients mentioning symptoms contralateral to the side on which HA coverage was performed. In all these claudication cases, a significant iliac or femoral stenosis was present. Those operated on

Table V. Patient outcomes through follow-up period

Variable (per patient analysis)	NE (n = 113)	CE (n = 84)	*P* value
Clinical follow-up, days	681.8 ± 299.6 (21-1265)	701.2 ± 295.1 (69-1276)	.530
Follow-up to last image, days	641.6 ± 327.6 (13-1265)	665.5 ± 321.7 (6-1276)	.464
All-cause mortality	16.8 (19/113)	10.7 (9/113)	.225
Cardiac failure	5	2	
Respiratory insufficiency	5	2	
Renal failure	1	1	
Sepsis (UTI)	4	2	
Cancer	4	2	
CHA-related mortality	0	0	
All-cause secondary intervention	15.0 (17/113)	20.2 (17/84)	.340
Any type endoleak	15.0 (17/113)	25.0 (21/84)	.080
Type I or III	5	7	
Type II	12	14	
Variable (per covered HA analysis)	**NE (n = 134)**	**CE (n = 91)**	***P* value**
CHA-related endoleak	3.0 (4/134)	5.5 (5/91)	.346
Type I distal	3	1	
Type III limb connection	0	1	
Type II from HA	1	3	
CHA-related secondary intervention	7.5 (10/134)	15.4 (14/91)	.057
For endoleak	2.2 (3/134)	2.2 (2/91)	.984
For occlusion or stenosis	5.2 (7/134)	13.2 (12/91)	.035[a]

CE, Coil embolization or plugging; *CHA-related,* at covered hypogastric artery side; *HA,* hypogastric artery; *NE,* without prior coil embolization or plugging; *UTI,* urinary tract infection.
Values are reported as mean ± standard deviation or frequencies (%) (n/N). Denominator differs when there are missing values.
[a]Significantly different.

were free from complaints afterward, suggesting that none of the complaints were related to HA occlusion.

DISCUSSION

The incidence of AAA is increasing and is particularly obvious in the elderly. With the development of new techniques and an increase in standards of living, more AAA patients are likely to undergo an EVAR procedure.[20] With EVAR extending to the external iliac artery, it is controversial whether excluding the HA with coils is more effective at preventing HA-related endoleaks than without coil embolization. The 2011 European guidelines on the management of AAAs state that HA embolization is usually preferred to simple endograft coverage, based on level IV evidence (case series) and a grade C of recommendation (level IV studies).[21] A recently published meta-analysis on this topic stated that no benefits of coil embolization exist but also concluded that available studies are of small series only and with a variety of reasons for sole HA coverage, and therefore they are difficult to compare.[22] Hence, larger studies with sufficient follow-up will contribute to the discussion and help in making balanced choices in HA management.

The ENGAGE Registry was undertaken to quantify the performance of the Endurant endograft within the context of contemporary practice. Because some consider it a weakness of a study to be industry funded, Medtronic wanted to prove otherwise with this initiative. The quality of registries depends on the quality of reporting. Therefore, incomparable to historic registries, large efforts for on-site quality control and continual monitoring were made to guarantee completeness of data reports and thus high quality and reliability of data.[19] Although not specially designed for our hypothesis, we believe that the ENGAGE database is of sufficient quality to use for meaningful analyses concerning our topic. Extrapolation of our findings to other commercially available databases may not be justified as only Endurant cases are included, which may be considered a limitation of using the ENGAGE Registry for our study. The proportion of EVAR patients in the ENGAGE Registry who underwent coverage over the HA origin was within the ranges as reported in the literature,[11-18,23] and no iliac branched devices were included. Remarkably, a minority of our cohort received pre-emptive coil embolization, despite that this is considered a standard of practice. The tide might already have shifted toward sole graft coverage in recent years, and coil embolization is less popular than thought. Both groups in this study demonstrate comparable baseline characteristic with respect to

clinical risk factors as well as CIA morphology, making them suitable for comparative analysis.

Similar to previous studies, we found longer operation time and X-ray exposure for CE patients.[22] We did not find significant differences in contrast agent use, blood loss, and postoperative hospitalization. Approximately 50% of CE patients were treated following a two-step approach that includes an extra intervention for coil embolization with fluoroscopy and hospital admission. Unfortunately, the numbers of coils required, the size of the coils, and the extent of coil embolization were not registered in the database, making it impossible to perform a cost analysis. Previous studies estimate the average cost for HA embolization alone to be an estimated U.S. $3500.[10]

Our study reported several patients with unrelated endoleaks at completion angiography that were left untreated by the operator. Only a small minority of the endoleaks were HA related. During follow-up, the occurrence of HA-related endoleaks was also scarce, and no significant differences were found between both groups. The 3.0% incidence rate of HA-related endoleaks in the NE group is higher than the 0% that is often mentioned in small series,[11,12,14,23-26] but it does not exceed the incidence rate in the study of Papazoglou et al,[16] notwithstanding the fact that we also included distal type I and type III endoleaks in our analysis. Notably, also in the CE group, type II endoleaks appeared. Nonetheless, there was only a 2.2% incidence of secondary interventions to resolve HA-related endoleaks. All of them were type IB or type III endoleaks, tackled by minimally invasive means with endovascular limb extension.

Possible reasons that such small numbers of type II endoleaks occur in simple graft-covered HAs were mentioned earlier by our research group.[22] We found that in the majority of cases and despite the presence of a CIA aneurysm, a short narrow-caliber segment is present at the iliac bifurcation. This tapering near the origin of the HA is probably sufficient to provide adequate seal and to allow thrombosis of the main trunk of the HA.

The occurrence of clinically relevant occlusions of the endograft limbs in the studied cohort is not surprisingly high. In another ENGAGE publication, Faure et al[27] identified extension of a limb graft into the external iliac as the strongest predictor for the occurrence of limb occlusions. Coil embolization was not included as an independent factor in their analysis. We found a significant difference of limb graft occlusion in favor of the NE group, whereas the incidence of secondary intervention required for limb occlusions was approximately 2.5 times higher in cases with pre-emptive coil embolization. We cannot give any good explanation for the higher rates for limb occlusion found after coil embolization.

No colonic ischemia or gluteal necrosis was reported in our study. Erectile dysfunction and buttock claudication were not mentioned as adverse events in this subcohort of the ENGAGE Registry. Reports of claudication of the lower extremities were made but considered not related to coil embolization or its omission because onset of complaints of claudication was late and its appearance reducible to cases of limb occlusion. Incidence rates in the literature of >50% of buttock claudication and 40% of erectile dysfunction in patients with unilateral HA embolization and even higher in bilateral HA occlusion[28,29] led us to believe that there must have been considerable underreporting of these symptoms in the ENGAGE Registry. Sexual dysfunction and buttock claudication were not routinely queried in all participating clinics. Therefore, limited value should be attributed to the reported absence of physical complications in our population.

Another limitation of this study is that there were no given explanations of the chosen EVAR strategy, whether HA coverage was intentional or accidental and why the choice for coil embolization or sole coverage was made. This causes a risk for selection bias and the comparison of unequal groups, namely, a large number of cases of incidental HA coverage in the NE group and selected cases of worse anatomy left for coil embolization. However, of great importance, iliac morphology and other anatomic measurements were comparable between both groups, leaving us to believe that an honest comparison is perfectly possible. Also, the studied population represented >80% of cases of patients with concomitant CIA aneurysms together with >50% of insufficient nonaneurysmatic CIAs left for adequate distal sealing, suggesting that there was no large proportion of cases with incidental HA coverage. Despite the extensive number of anatomic measurements recorded in the database, it remains insufficient to convert these into a perfect image of iliac morphology, which would otherwise allow us to detect a subgroup of iliacs that require prior coil embolization. Furthermore, it has not been documented if the HA was still patent before its orifice was covered. Equally, we cannot report on CIA growth because the ENGAGE database did not include iliac artery diameters at follow-up.

CONCLUSIONS

This study shows that HA coverage with the Endurant endograft without prior coil embolization does not increase the incidence of endoleak or related secondary interventions. In taking into account that embolization is usually costly and often requires multiple interventions and longer procedures with fluoroscopic guidance, these findings suggest that omission of coil embolization may be a more resource-effective strategy whenever HA coverage is required.

AUTHOR CONTRIBUTIONS

Conception and design: RS, PB, MS, JT, PC
Analysis and interpretation: RS, PB, PC
Data collection: Not applicable
Writing the article: RS, PB, MS, JT, PC

Critical revision of the article: RS, PB, MS, JT, PC
Final approval of the article: RS, PB, MS, JT, PC
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REFERENCES

1. Parodi JC, Palmaz JC, Barone HD. Transfemoral intraluminal graft implantation for abdominal aortic aneurysms. Ann Vasc Surg 1991;5:491-9.
2. Sachs T, Schermerhorn M, Pomposelli F, Cotterill P, O'Malley J, Landon B. Resident and fellow experiences after the introduction of endovascular aneurysm repair for abdominal aortic aneurysm. J Vasc Surg 2011;54:881-8.
3. Hobo R, Sybrandy JE, Harris PL, Buth J. Endovascular repair of abdominal aortic aneurysms with concomitant common iliac artery aneurysm: outcome analysis of the EUROSTAR Experience. J Endovasc Ther 2008;15:12-22.
4. Armon MP, Wenham PW, Whitaker SC, Gregson RH, Hopkinson BR. Common iliac artery aneurysms in patients with abdominal aortic aneurysm. Eur J Vasc Endovasc Surg 1998;15:155-7.
5. Rouwet EV, Torsello G, de Vries JP, Cuypers P, van Herwaarden JA, Eckstein HH, et al. Final results of the prospective European trial of the Endurant stent graft for endovascular abdominal aortic aneurysm repair. Eur J Vasc Endovasc Surg 2011;42:89-97.
6. Ghosh J, Murray D, Paravastu S, Farquharson F, Walker MG, Serracino-Inglott F. Contemporary management of aorto-iliac aneurysms in the endovascular era. Eur J Vasc Endovasc Surg 2009;37:182-8.
7. Criado FJ, Wilson EP, Velazquez OC, Carpenter JP, Barker C, Wellons E, et al. Safety of coil embolization of the internal iliac artery in endovascular grafting of abdominal aortic aneurysms. J Vasc Surg 2000;32:684-8.
8. Wolpert LM, Dittrich KP, Hallisey MJ, Allmendinger PP, Gallagher JJ, Heydt K, et al. Hypogastric artery embolization in endovascular abdominal aortic aneurysm repair. J Vasc Surg 2001;33:1193-8.
9. Cynamon J, Lerer D, Veith FJ, Taragin BH, Wahl SI, Lautin JL, et al. Hypogastric artery coil embolization prior to endoluminal repair of aneurysms and fistulas: buttock claudication, a recognized but possibly preventable complication. J Vasc Interv Radiol 2000;11:573-7.
10. Ha CD, Calcagno D. Amplatzer Vascular Plug to occlude the internal iliac arteries in patients undergoing aortoiliac aneurysm repair. J Vasc Surg 2005;42:1058-62.
11. Wyers MC, Schermerhorn ML, Fillinger MF, Powell RJ, Rzucidlo EM, Walsh DB, et al. Internal iliac occlusion without coil embolization during endovascular abdominal aortic aneurysm repair. J Vasc Surg 2002;36:1138-45.
12. Lee CW, Kaufman JA, Fan CM, Geller SC, Brewster DC, Cambria RP, et al. Clinical outcome of internal iliac artery occlusions during endovascular treatment of aortoiliac aneurysmal diseases. J Vasc Interv Radiol 2000;11:567-71.
13. Farahmand P, Becquemin JP, Desgranges P, Allaire E, Marzelle J, Roudot-Thoraval F. Is hypogastric artery embolization during endovascular aortoiliac aneurysm repair (EVAR) innocuous and useful? Eur J Vasc Endovasc Surg 2008;35:429-35.
14. Bharwani N, Raja J, Choke E, Belli AM, Thompson MM, Morgan RA, et al. Is internal iliac artery embolization essential prior to endovascular repair of aortoiliac aneurysms? Cardiovasc Intervent Radiol 2008;31:504-8.
15. Tefera G, Turnipseed WD, Carr SC, Pulfer KA, Hoch JR, Acher CW. Is coil embolization of hypogastric artery necessary during endovascular treatment of aortoiliac aneurysms? Ann Vasc Surg 2004;18:143-6.
16. Papazoglou KO, Sfyroeras GS, Zambas N, Konstantinidis K, Kakkos SK, Mitka M. Outcomes of endovascular aneurysm repair with selective internal iliac artery coverage without coil embolization. J Vasc Surg 2012;56:298-303.
17. Luo H, Huang B, Yuan D, Yang Y, Xiong F, Zeng G, et al. 8-Year long-term outcome comparison: two ways to exclude the internal iliac artery during endovascular aorta repair (EVAR) surgery. PLoS One 2015;10:e0130586.
18. Rajesparan K, Partridge W, Refson J, Abidia A, Aldin Z. The risk of endoleak following stent covering of the internal iliac artery during endovascular aneurysm repair. Clin Radiol 2014;69:1011-8.
19. Stokmans RA, Teijink JA, Forbes TL, Bockler D, Peeters PJ, Riambau V, et al. Early results from the ENGAGE registry: real-world performance of the Endurant Stent Graft for endovascular AAA repair in 1262 patients. Eur J Vasc Endovasc Surg 2012;44:369-75.
20. Schoder M, Zaunbauer L, Holzenbein T, Fleischmann D, Cejna M, Kretschmer G, et al. Internal iliac artery embolization before endovascular repair of abdominal aorta aneurysm: frequency, efficacy, and clinical results. AJR Am J Roentgenol 2001;177:599-605.
21. Moll FL, Powell JT, Fraedrich G, Verzini F, Haulon S, Waltham M, et al. Management of abdominal aortic aneurysms clinical practice guidelines of the European Society for Vascular Surgery. Eur J Vasc Endovasc Surg 2011;41:S1-58.
22. Kontopodis N, Tavlas E, Papadopoulos G, Galanakis N, Tsetis D, Ioannou CV. Embolization or simple coverage to exclude the internal iliac artery during endovascular repair of aortoiliac aneurysms? Systematic review and meta-analysis of comparative studies. J Endovasc Ther 2017;24:47-56.
23. Stokmans RA, Willigendael EM, Teijink JA, Ten Bosch JA, van Sambeek MR, Cuypers PW. Challenging the evidence for pre-emptive coil embolisation of the internal iliac artery during endovascular aneurysm repair. Eur J Vasc Endovasc Surg 2013;45:220-6.
24. Karch LA, Hodgson KJ, Mattos MA, Bohannon WT, Ramsey DE, McLafferty RB. Adverse consequences of internal iliac artery occlusion during endovascular repair of abdominal aortic aneurysms. J Vasc Surg 2000;32:676-83.
25. Sheehan MK, Hagino RT, Canby E, Wholey MH, Postoak D, Suri R, et al. Type 2 endoleaks after abdominal aortic aneurysm stent grafting with systematic mesenteric and lumbar coil embolization. Ann Vasc Surg 2006;20:458-63.
26. Nevala T, Biancari F, Manninen H, Matsi P, Makinen K, Ylonen K, et al. Inferior mesenteric artery embolization before endovascular repair of an abdominal aortic aneurysm: effect on type II endoleak and aneurysm shrinkage. J Vasc Interv Radiol 2010;21:181-5.
27. Faure EM, Becquemin JP, Cochennec F; ENGAGE collaborators. Predictive factors for limb occlusions after endovascular aneurysm repair. J Vasc Surg 2015;61:1138-45.
28. Rayt HS, Bown MJ, Lambert KV, Fishwick NG, McCarthy MJ, London NJ, et al. Buttock claudication and erectile dysfunction after internal iliac artery embolization in patients prior to endovascular aortic aneurysm repair. Cardiovasc Intervent Radiol 2008;31:728-34.
29. Mehta M, Veith FJ, Ohki T, Cynamon J, Goldstein K, Suggs WD, et al. Unilateral and bilateral hypogastric artery interruption during aortoiliac aneurysm repair in 154 patients: a relatively innocuous procedure. J Vasc Surg 2001;33:S27-32.

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