RWD141

Endovascular treatment of iliac and aorto-iliac aneurysms using iliac-branched devices in France: Analysis of a French national insurance claims database comparing two iliac-branched devices

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BACKGROUND

Common iliac artery aneurysm is found in more than one third of abdominal aortic aneurysms and occurs bilaterally in 30% to 50% of cases; the annual incidence in Western populations is approx. 0.5%.[1] As for any aortic aneurysm, the most feared outcome is rupture, which increases with the diameter of the aneurysm and is fatal in more than 8 out of 10 cases.[2]

Endovascular aneurysm repair (EVAR) is the strategy used most widely in the management of ruptured iliac artery aneurysms – as opposed to conventional open surgery – as it reduces blood loss, the risk of complications and morbidity and mortality. It remains a technical challenge, however.[1]

Very few devices are available in France for EVAR of common iliac artery aneurysms or aorto-iliac aneurysms with bilateral iliac involvement. To date, two devices are available on the market and reimbursed by the French National Health Insurance Fund: GORE® EXCLUDER® Iliac Branch Endoprosthesis (IBE) and COOK® ZENITH® Branch Iliac Endovascular Graft (ZENITH Device).

Given the lack of real world data on the long-term follow-up of a cohort representative of patients implanted with IBE in France, the French National Authority for Health (Haute Autorité de Santé, HAS) asked W. L. Gore & Associates to perform a post-registration study to fill this gap. Real-life outcomes were compared against those of the only comparator available in France, namely the ZENITH Device.

OBJECTIVES

The objectives of this retrospective, longitudinal study were to describe and to compare, in real-life conditions, mid-term morbidity/mortality between patients receiving the IBE and those receiving the ZENITH Device, as well as morbidity with death as a competing risk.

METHODS

Source of data and population

The French National Healthcare Data System (Système National des Données de Santé, SNDS) – which collects inpatient and outpatient health care resource utilization (HCRU) data for almost the entire French population (>99%) – was used to select all patients implanted with the IBE (Group 1) or the ZENITH Device (Group 2) in France, whether at public or private health institutions. Morbidity/mortality was assessed among patients covered by the general scheme, i.e., with reliable mortality data.

Iliac branch device (IBD) implantation and events of interest were identified from LPPR *(Liste des Produits et Prestations Remboursables)* codes for the implant device and/or relevant CCAM *(Classification Commune des Actes Médicaux)* surgical procedure codes.

Study population

- Patients with primary implantation of (1) IBE or (2) ZENITH Device
- Concomitant CCAM surgical code for implantation of an endoprosthesis
- No concomitant implantation of IBE and ZENITH Device during index stay
- EVAR from the same manufacturer during index stay or in the five years prior to the index date
- No fenestrated or branched EVAR

Study settings

- Index date T_0: first implantation of IBD (either IBE or ZENITH Device)
- Inclusion period: from November 1, 2017 (i.e., IBE inclusion on the list of refundable devices) to December 31, 2019
- Follow-up: from T_0 to (i) December 31, 2020 (data cut-off), (ii) death, or (iii) the end of health insurance coverage as recorded in the database
- Clinical characteristics assessment before implantation: 4-year history of HCRU before T_0

Statistical methods

Propensity score matching

To ensure that the two groups were well-balanced at implantation and the influence of potential confounding factors was minimized, individual propensity score matching was conducted using logistic regression with the device type as the dichotomous dependent variable and different baseline characteristics as the independent variables, such as age, gender, comorbidities at the index date, antiplatelet drug prescription, characteristics of the index stay (diagnoses, duration, severity etc.) and type of hospital where the IBD implantation was performed.

Outcome

Morbidity/mortality was assessed through a composite criterion of event-free survival by documenting the following endpoints: all-cause mortality, endovascular aortic reintervention (EAR), open aortic reintervention (OAR), branch thrombectomy (BT) (the latter three qualifying as reinterventions) and embolization of any type of endoleak (including type II). Time to morbidity/mortality was assessed in both groups with Kaplan-Meier curves and survival probabilities, and the groups were compared using a log-rank test. Morbidity events were additionally assessed with death as a competing risk. Cumulative incidence curves per group were presented, as well as a Gray's test to compare the two groups.

RESULTS

Characteristics of the patients of the two groups

A total of 231 patients were identified in each group. Mean age was 71.9 ± 8.8 and 73.5 ± 9.0 years, respectively; in both groups, 96.1% were men.

Table 1: **Comparison of patient characteristics between the (1) IBE and (2) ZENITH Device populations before and after linkage**

	BEFORE LINKAGE			AFTER LINKAGE		
	Stat. test	(1) IBE N=361	(2) ZENITH Device N=281	Stat. test	(1) IBE N=231	(2) ZENITH Device N=231
Male, n (%)	NS	347 (96.1)	270 (96.1)	NS	222 (96.1)	222 (96.1)
Age at T_0 (years), mean (SD)	P = 0.043	72.4 (9.0)	73.8 (8.8)	NS	71.9 (8.8)	73.5 (9.0)
Center size group at T_0 **≤ 10, n (%)** **[10-50], n (%)** **> 50, n (%)**	NS	12 (3.3) 110 (30.5) 239 (66.2)	7 (2.5) 91 (32.4) 183 (65.1)	NS	7 (2.7) 82 (31.2) 174 (66.2)	6 (2.3) 85 (32.3) 172 (65.4)
Comorbidities at T_0, n (%)						
Hypertension	NS	282 (78.1)	229 (81.5)	NS	183 (79.2)	186 (80.5)
Diabetes	NS	57 (15.8)	37 (13.2)	NS	34 (14.7)	34 (14.7)
COPD	NS	67 (18.6)	59 (21.0)	NS	46 (19.9)	47 (20.3)
Chronic respiratory insufficiency	P = 0.032	15 (4.2)	23 (8.2)	NS	11 (4.8)	12 (5.2)
Smoking	NS	93 (25.8)	84 (29.9)	NS	64 (27.7)	65 (28.1)
Chronic alcoholism	NS	22 (6.1)	22 (7.8)	NS	17 (7.4)	14 (6.1)
Myocardial infarction	NS	1 (0.3)	1 (0.4)	NS	1 (0.4)	1 (0.4)
Heart failure	NS	28 (7.8)	21 (7.5)	NS	17 (7.4)	18 (7.8)
Coronary artery disease	NS	128 (35.5)	108 (38.4)	NS	87 (37.7)	87 (37.7)
Cardiac rhythm disorders	NS	98 (27.1)	93 (33.1)	NS	63 (27.3)	68 (29.4)
End-stage renal disease	NS	32 (8.9)	35 (12.5)	NS	23 (10.0)	27 (11.7)
Malignant neoplasm	NS	77 (21.3)	68 (24.2)	NS	51 (22.1)	54 (23.4)
Peripheral artery disease	NS	90 (24.9)	75 (26.7)	NS	55 (23.8)	61 (26.4)
History of stroke	NS	24 (6.6)	26 (9.3)	NS	20 (8.7)	20 (8.7)
Events before T_0, n (%)						
Coronary revascularization	NS	41 (11.4)	44 (15.7)	NS	25 (10.8)	32 (13.9)
Aortic surgery	NS	13 (3.6)	6 (2.1)	NS	5 (2.2)	5 (2.2)
Antiplatelet drug use	NS	237 (65.7)	196 (69.8)	NS	153 (66.2)	157 (68.0)

NS: non-significant (p>0.05)

Morbidity/mortality composite criterion (event-free survival)

From T0 (implantation), a median follow-up of 23.1 months (Q1-Q3: 15.7-29.0) and 23.3 months (Q1-Q3: 16.1-31.5) was noted for the (1) IBE and (2) ZENITH Device populations, respectively, with a maximum of 37.6 months and 38.0 months.

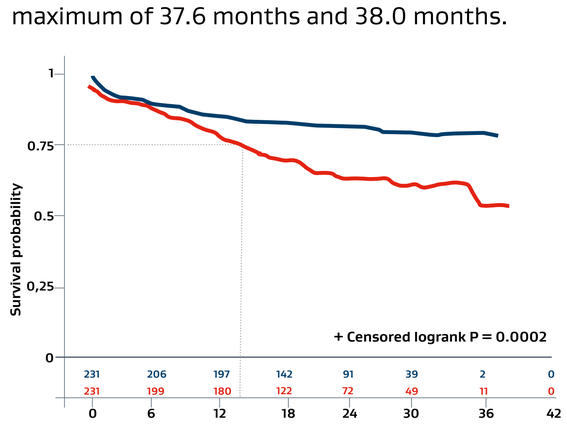

Figure 1. **Time to morbimortality in patients implanted with IBE (population (1)) and ZENITH Device (population (2))**

Morbidity/mortality composite criterion (event-free survival)

The crude mortality rate at one year was 5% in group 1 versus 6% in group 2 and at two years 7% in group 1 versus 14% in group 2. The proportion of patients with no morbidity/mortality event was 85.0% (95%CI [80.0; 89.0]) versus 79.0% [73.0; 83.0] at one year and 81% [75.0; 86.0] versus 63% [55.0; 69.0] at two years, respectively. Over the entire follow-up period, the morbidity/mortality event rate differed significantly in favor of group 1 (HR: 0.51, 95%CI [0.35; 0.73], p=0.0003) (Figure 1: HR of morbimortality, population (1) IBE versus population (2) ZENITH Device, for the overall available follow-up period). Among the components, three significantly favored IBE: reintervention for EAR (HR: 0.48, 95%CI:[0.27;0.84]), BT (HR: 0.35, 95%CI: [0.13; 0.98]), OAR (HR: 0.21, 95%CI: [0.06; 0.73]).

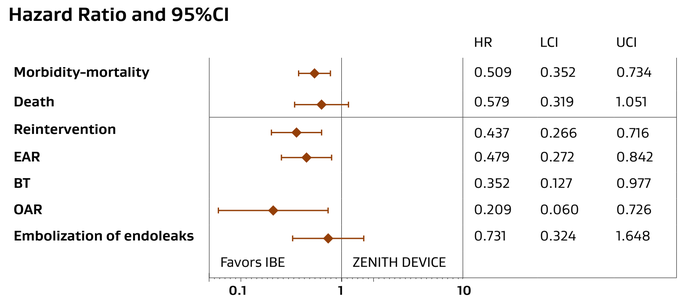

Figure 2. **HR of morbimortality, population (1) IBE versus population (2) ZENITH Device, for the overall follow-up period.**

When excluding embolization of endoleaks from the composite criterion, the proportion of patients free of events was consistently higher in population (1) IBE (88.0% (95%CI [83.0; 92.0]) and 83.0% (95%CI [77.0; 88.0]) at 1 year and 3 years, respectively) than in population (2) ZENITH Device (80.0% (95%CI [75.0; 85.0]) and 56.0% (95%CI [44.0; 66.0]) at 1 year and 3 years, respectively).

CONCLUSIONS

This is one of the largest cohort studies of patients implanted with EVAR devices in France, assessing the treatment of aorto-iliac or iliac aneurysms in real-world treatment conditions, with a median follow-up of 2 years.

The IBE achieves higher morbidity/mortality event-free survival than the ZENITH Device, with a decrease in the morbidity/mortality risk of 49% over the entire post-implantation follow-up period (median of approx. 2 years for both groups). The decrease in morbidity risk (death as a competing event) was 46%. Future analyses over a longer follow-up period will enable us to assess these long-term results.

REFERENCES

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IQR=interquartile range; SD=standard deviation; CI=confidence interval

SNDS databases provided by CNAM; data controller: W. L. Gore & Associates; processing implementation officer: RCTs.
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