Costs of Endovascular Treatment of Iliac and Aorto-iliac Aneurysms using Iliac-branched Devices in France

RWD3

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BACKGROUND

Common iliac artery aneurysms present bilaterally in 30%-50% of cases and occur in over one third of abdominal aortic aneurysms. The annual incidence in Western populations is approx. 0.5%.[1] The most feared outcome, as with any aortic aneurysm, is **rupture**, which increases with aneurysm diameter and **is fatal in over 80% of cases.**[2]

Endovascular aneurysm repair (EVAR) is the preferred method for managing iliac artery aneurysm ruptures as it reduces blood loss, complications and mortality compared to conventional open surgery, though it remains technically challenging.[1] In France, very few iliac branch devices (IBDs) are available for EVAR of common iliac artery aneurysms or aorto-iliac aneurysms with bilateral iliac involvement. To date, two devices are eligible for reimbursement: GORE® EXCLUDER® Iliac Branch Endoprosthesis (IBE) and 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. In addition to clinical outcomes, health care resource utilization (HCRU) and costs after implantation were recorded and compared between the two IBDs available on the French market, namely IBE and the ZENITH Device.

OBJECTIVES

The objectives were to compare HCRU and costs from the perspective of the French National Health Insurance Fund (amounts reimbursed) at index date, 1 and 2 years and over the entire follow-up period for patients implanted with either of the two available IBDs: IBE and ZENITH Device.

METHODS

Source of data and population

The French National Healthcare Data System (Système National des Données de Santé, SNDS) – which collects health care resource utilization (HCRU) data for almost the entire French population (>99%) – was used to identify all patients who had received the IBE (group 1) or ZENITH Device (group 2) implants in France whether at public or private health institutions. IBD implantation was identified from a combination of implant code and relevant medical procedure codes.

Direct medical (inpatient/outpatient and ambulatory care) and non-medical (transportation) costs were retrieved, as well as some indirect costs (sick leave, daily allowances, disability pensions).

Global costs were retrieved for inpatient and outpatient care, as well as IBD-specific costs.

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., IBD inclusion on the list of refundable devices) to December 31, 2019
- Follow-up: from T_0 to December 31, 2020
- Clinical characteristics assessment before implantation: 4-year history of HCRU before T_0

Statistical methods

Propensity score matching

To ensure comparability between the two groups, individual propensity score matching was performed based on demographics and clinical characteristics at the index date (including sex, age, center size, comorbidities and the use of antiplatelet drugs). The matching model was specifically designed to pair patients within the same insurance scheme (general scheme or otherwise).

Outcome

Costs, defined as the amounts reimbursed by the French National Health Insurance Fund, were calculated at each time point and adjusted to reflect euro prices as at 2021 euros based on INSEE¶ annual reports [3, 4, 5]. Comparisons were made using descriptive analysis and the Mann-Whitney U test. Additionally, total costs over the follow-up period were compared using a multivariate generalized linear model with gamma distribution, adjusting for demographic and clinical characteristics.

RESULTS

Characteristics of the patients of the two groups

A total of 263 patients were identified in each group *(Table 1)*. Mean age was 72.5 (SD 8.9) and 73.8 (SD 8.8) years, respectively; 96.2% and 95.8% were men, respectively. The median follow-up was 23 (IQR 14.3) months.

¶ INSEE : Institut National de la Statistique et des Etudes Economiques

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=263	(2) ZENITH Device N=263
Male, n (%)	NS	347 (96.1)	270 (96.1)	NS	253 (96.2)	252 (95.8)
Age at T_0 (years), mean (SD)	P = 0.043	72.4 (9.0)	73.8 (8.8)	NS	72.5 (8.9)	73.8 (8.8)
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	209 (79.5)	213 (81.0)
Diabetes	NS	57 (15.8)	37 (13.2)	NS	39 (14.8)	36 (13.7)
COPD	NS	67 (18.6)	59 (21.0)	NS	53 (20.2)	51 (19.4)
Chronic respiratory insufficiency	P = 0.032	15 (4.2)	23 (8.2)	NS	13 (4.9)	14 (5.3)
Smoking	NS	93 (25.8)	84 (29.9)	NS	69 (26.2)	74 (28.1)
Chronic alcoholism	NS	22 (6.1)	22 (7.8)	NS	17 (6.5)	16 (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	19 (7.2)	20 (7.6)
Coronary artery disease	NS	128 (35.5)	108 (38.4)	NS	97 (36.9)	99 (37.6)
Cardiac rhythm disorders	NS	98 (27.1)	93 (33.1)	NS	77 (29.3)	84 (31.9)
End-stage renal disease	NS	32 (8.9)	35 (12.5)	NS	26 (9.9)	30 (11.4)
Malignant neoplasm	NS	77 (21.3)	68 (24.2)	NS	58 (22.1)	60 (22.8)
Peripheral artery disease	NS	90 (24.9)	75 (26.7)	NS	62 (23.6)	68 (25.9)
History of stroke	NS	24 (6.6)	26 (9.3)	NS	22 (8.4)	24 (9.1)
Events before T_0, n (%)						
Coronary revascularization	NS	41 (11.4)	44 (15.7)	NS	30 (11.4)	37 (14.1)
Aortic surgery	NS	13 (3.6)	6 (2.1)	NS	5 (1.9)	5 (1.9)
Antiplatelet drug use	NS	237 (65.7)	196 (69.8)	NS	177 (67.3)	179 (68.1)

NS: non-significant (p>0.05)

The most frequent reasons for admission for implantation were similar in both groups: abdominal aortic aneurysm, without mention of rupture (59.3% and 57.3% of patients, respectively) and aneurysm and dissection of iliac artery (30.2% and 31.3% of patients). The median length of stay was lower for population (1) (4 days; IQR: [3.0; 6.0]) than for population (2) (5 days; IQR: [4.0, 7.0]). Approximately 60.0% of the implantations in both groups were performed within the public sector.

TOTAL COST

Over the whole follow-up period, the adjusted estimated mean cost per patient in population (1) IBE was €30,012 (95% CI [€29,304; €30,720]), which was significantly lower (P = 0.0030) than in population (2) ZENITH Device at €34,206 (95% CI [€33,473; €34,939]).

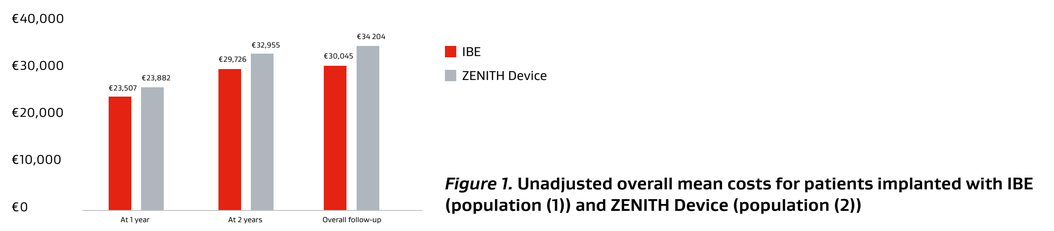

Figure 1. **Unadjusted overall mean costs for patients implanted with IBE (population (1)) and ZENITH Device (population (2))**

OUTPATIENT COSTS

Over the whole follow-up period, outpatient care cost an average of €6,803 in population (1) IBE and €8,567 in population (2) ZENITH Device, with drugs and paramedical consultations accounting for the largest share of outpatient expenditure: €1,829 and €1,136 in population (1) IBE and €2,404 and €1,565 in population (2) ZENITH Device, respectively.

HOSPITALIZATION COSTS

Over the whole follow-up period, resuscitation and/or intensive care cost an average of €567 in the (1) IBE population and €999 in the (2) ZENITH Device population *(Figure 3)*.
No significant differences were identified.

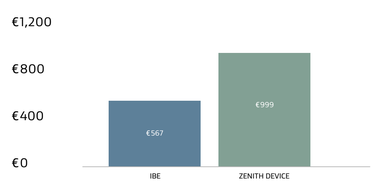

Figure 3. **Mean cost of resuscitation and/or intensive care for patients implanted with IBE (population (1)) and ZENITH Device (population (2))**

COST OF MEDICAL DEVICES OF INTEREST (IMPLANTS)

The total mean cost of medical devices of interest (IBE and ZENITH Device) was €10,565 in population (1) IBE and €9,478 in population (2) ZENITH Device *(Figure 4)*.

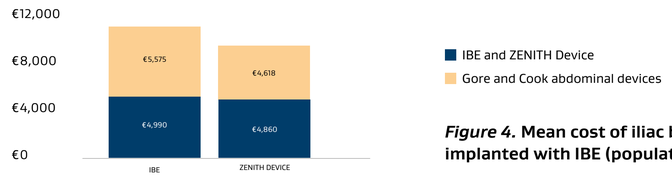

Figure 4. **Mean cost of iliac branch and abdominal endoprosthesis for patients implanted with IBE (population (1)) and ZENITH Device (population (2))**

CONCLUSIONS

The SNDS is an exhaustive medical administrative database that can provide real-world cost data and enabled the analysis of one of the largest cohorts of patients implanted with an IBE or a ZENITH Device in France as treatment for an aorto-iliac or iliac aneurysm in real-world conditions, with a median follow-up of 2 years.

In addition to the benefit to morbidity/mortality in favor of the IBE (cf. poster 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),* endovascular repair of aorto-iliac aneurysms was associated with lower health care resource consumption and costs when using the IBE rather than the ZENITH Device in real life.

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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. Study registered with the Health Data Hub (CNIL authorization No. DR-2021-111 of April 16, 2021).