Endovascular management of iliac and aorto-iliac aneurysms and impact on morbidity/mortality in France: a French national insurance claims database analysis (SNDS)

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BACKGROUND

Common iliac artery aneurysms (CIA) are present in more than a third of abdominal aortic aneurysms (AAA), with a reported annual incidence rate of 0.5 percent in Western populations.[1] The life-threatening complications such as iliac artery aneurysm ruptures, expand with the diameter of the aneurysm and are fatal in more than eight out of 10 cases.[2]

Endovascular aneurysm repair (EVAR) is the most widely-used strategy to manage iliac artery aneurysms – as opposed to the conventional approach of open surgery, which reduces blood loss, risk of complications and overall morbidity and mortality. However, this still remains a technical challenge.[1]

Very few devices are available in France for EVAR of CIA aneurysms or aorto-iliac aneurysms with bilateral iliac involvement. Among them, GORE® EXCLUDER® Iliac Branch Endoprosthesis (IBE) is included on the list of devices refundable in France since 2017.

With a lack of real-world evidence on long-term follow-up of a cohort representative of patients implanted with the IBE in France, the French Health Authority (Haute Autorité de Santé, HAS) requested W. L. Gore & Associates to conduct a post-registration study to fill this gap.

OBJECTIVE

The main objective was to utilize real-world evidence to estimate morbidity/mortality in patients implanted with the IBE in France.

METHODS

Source of data and population:

The French Healthcare Database System (Système National des Données de Santé, SNDS) — which gathers inpatient and outpatient health care resource use (HCRU) for a large proportion of the French population (> 99%). The SNDS was used to select all patients implanted with an IBE in France, in all public and private health institutions, since its availability on the market. Morbidity/mortality was assessed among patients covered by the General Scheme, i.e., with reliable mortality data.

IBE implantation and events of interest (see primary outcome) were identified by a concomitant combination of implant codes and relevant medical procedures codes.

Demographic and clinical characteristics (medical and treatment history) at implantation have been described, as well as features of implantation stay.

Study settings:

- Index date T_0: first implantation of the IBE
- Selection 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 December 31, 2020
- Clinical characteristics assessment: Four-year history of HCRU before T_0

Primary outcome:

Morbidity/mortality was defined as a composite criterion gathering all-cause death, aortic endovascular reintervention (AER, which was re-operations for endovascular aortic surgery such as abdominal or iliac angioplasty or EVAR), embolization of any type of endoleak – including type II, branch thrombectomy and bypass. Morbidity events were additionally assessed with death as a competing risk.

As implantation side is unknown in the SNDS, any endovascular aortic surgery after T_0 was considered as an AER (worst-case scenario). Some of them being possibly performed on the contra-lateral side. Furthermore, a sensitivity analysis was performed classifying additional endovascular aortic surgery as an intervention on the contra-lateral side (best-case scenario).

RESULTS

(i) Characteristics of patients implanted with IBE

A total of 361 patients were implanted with an IBE. At T_0, they were aged 72.4 years old on average (SD*: 9.0) with a maximum age of 93.8 years and a minimum age of 49.9 years. The majority of patients were male (96.1%). Main comorbidities at T_0 are presented in *Table 1*.

Table 1. Main comorbidities of patients implanted with IBE at T_0

	Patients implanted with IBE N = 361		Patients implanted with IBE N = 361
Hypertension	282 (78.1)	Diabetes	57 (15.8)
Coronary artery disease	128 (35.5)	End-stage renal disease	32 (8.9)
Cardiac rhythm disorders	98 (27.1)	History of stroke	24 (6.6)
Smoking	93 (25.8)	Heart failure	28 (7.8)
Peripheral artery disease	90 (24.9)	Chronic alcoholism	22 (6.1)
Malignant neoplasm	77 (21.3)	Chronic respiratory insufficiency	15 (4.2)
Chronic obstructive pulmonary disease	67 (18.6)		

(ii) Morbidity/mortality at one and two years of patients implanted with IBE

Among patients implanted with IBE, 315 patients (87.3%) were in the General Scheme and could be assessed for morbidity/mortality. Patients from the General Scheme did not significantly differ from patients from other schemes (n = 46) with the exception of age – younger (71.8 ± 8.8 vs 76.3 ± 9.2, *P* = 0.001) – and for the proportion of cardiac rhythm disorders – less frequent (24.8% vs 43.5%, *P* = 0.008).

From T_0, a median follow-up of 23.1 months (Q1 - Q3: 15.7-29.0) was available and a maximum of 37.6 months.

Due to the paucity of events (65) and the high number of censors† after the first year of follow-up (by design), the median time to occurrence of the composite criterion could not be estimated (*Figure 1*).

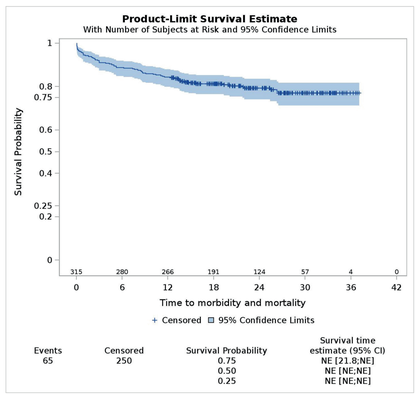

Figure 1. Time to morbidity-mortality

The proportion of patients free from any morbidity/mortality event after IBE implantation was estimated as 84.0% (95CI [80.0 ; 88.0]) and 79.0% [74.0 ; 84.0] at one year and two years after implantation, respectively (*Table 2*).

Table 2. Proportion of patients [95% CI] remaining free of morbidity/mortality composite criterion and its components

Time (months)	Morbidity/mortality composite criterion	All-cause death	Embolization of endoleaks	AER	Branch thrombectomy	Secondary bypass surgery
12	84.0 [80.0 ; 88.0]	96.0 [93.0 ; 97.0]	96.0 [93.0 ; 98.0]	92.0 [89.0 ; 95.0]	98.0 [95.0 ; 99.0	99.0 [97.0 ; 100.0]
24	79.0 [74.0 ; 84.0]	93.0 [89.0 ; 95.0]	95.0 [92.0 ; 97.0]	92.0 [88.0 ; 94.0]	97.0 [95.0 ; 99.0	98.0 [95.0 ; 99.0]

"Overall reintervention" defined as AER or branch thrombectomy or bypass surgery, the proportion of patients free from reintervention was estimated as 91.0% (95CI [87.0; 93.0]) and 89.0% [84.0; 92.0] at one year and two years after implantation, respectively.

In the sensitivity analysis with classification of all AERs as an intervention on the contra-lateral side (best-case scenario), 90.0% (95CI [86.0; 92.0]) and 85.0% [80.0; 88.0] of patients remained free of morbidity/mortality at one and two years after IBE implantation, respectively.

(iii) Morbidity with death as competing event at one and two years of patients implanted with IBE

Within the first and second year, 12.0% (95CI [9.0; 16.0]) and 15.0% (95CI [11.0; 19.0]) of patients would have presented a morbidity event, considering death as a competing event.

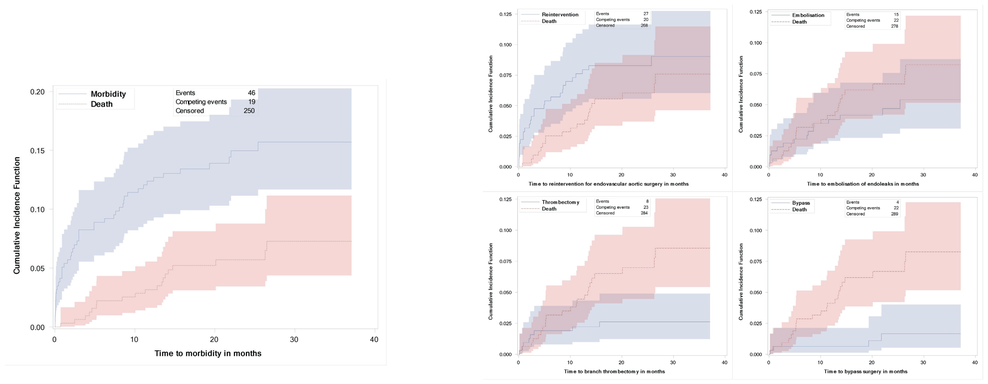

Figure 2. Time to morbidity, as composite criterion (left side) and for each of the morbidity events

Table 3. Proportion of patients [95% CI] with morbidity event as composite criterion and its components, with death as competing event

Time (months)	Morbidity composite criterion	AER	Embolization of endoleaks	Branch thrombectomy	Secondary bypass surgery
12	12.0 [9.0; 16.0]	8.0 [5.0; 11.0]	4.0 [2.0; 6.0]	2.0 [1.0; 4.0]	1.0 [0.0; 2.0]
24	15.0 [11.0; 19.0]	8.0 [6.0; 12.0]	5.0 [3.0; 8.0]	3.0 [1.0; 5.0]	2.0 [1.0; 4.0]

(iv) Features of the implantation stay

Mean length of stay for implantation was 5 ± 3.4 days; 60.7% of IBE implantations were performed within the public sector and 39.3% in the private sector. 9.1% of patients had at least one stay in resuscitation or intensive care unit, with a median length of stay of 2.0 days (Q1 - Q3: 1.0 ; 3.0). Less than 3% of patients had a level-4 DRG (disease related group), which corresponds to the highest level of severity.

CONCLUSIONS

To date, patient outcome data with IBE implantation for the management of iliac artery aneurysm is scarce. This study is the largest population-based study conducted on IBE in real-life settings to our knowledge, with a mid-term follow-up. It has been conducted on the SNDS and is almost exhaustive for the target population with limited loss-to-follow-up.

Although characteristics of patients for the assessment of morbidity-mortality was found to differ compared to the overall cohort of patients implanted in France for age and cardiac rhythm disorders, they were found to be aligned with the literature.[3,4]

Finally, these results showed morbidity/mortality outcomes in line with the literature; with 80% of patients implanted with IBE remaining free from any morbidity/mortality device-related event at two years after implantation. Upcoming analyses will allow the assessment of outcomes at five years.

REFERENCES

1. Giosdekos A, Antonopoulos CN, Sfyroeras GS, Moulakakis KG, Tsilimparis N, Kakisis JD, LazarisA, Chatziioannou A, Geroulakos G. The Use of Iliac Branch Devices for Preservation of Flow in Internal Iliac Artery during Endovascular Aortic Aneurysm Repair. *Journal of Vascular Surgery* 2020;71(6):2133-44. https://doi.org/10.1016/j.jvs.2019.10.087
2. Wautrecht, JC. Anévrismes des membres inférieurs. *Journal des Maladies Vasculaires* 2015;40(2):71-72. https://doi.org/10.1016/j.jmv.2014.12.063.3.
3. Dingemans, SA, Jonker FHW , Moll FL, van Herwaarden J. Aneurysm Sac Enlargement after Endovascular Abdominal Aortic Aneurysm Repair. *Annals of Vascular Surgery* 2016;31:229-38. https://doi.org/10.1016/j.avsg.2015.08.011
4. Masciello F, Fargion AT, Pratesi G, Dorigo W, Pratesi C. A Propensity Score-Matched Comparison of Two Commercially Available Iliac Branch Devices in Patients with Similar Clinical and Anatomic Preoperative Features. *Journal of Vascular Surgery* 2020;71(4): 1207-14. https://doi.org/10.1016/j.jvs.2019.07.058

* SD: standard deviation.

† Censors: patients without an event of interest and either change of scheme, or no HCRU for at least one year or at end of follow-up.

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).