Eur J Vasc Endovasc Surg (2025) 69, 847–854

A Prospective, Multicentre Registry on Thirty Day and One Year Outcomes of the E-liac Stent Graft System in Patients with Unilateral or Bilateral Aorto-iliac or Iliac Aneurysms: The PLIANTII Study

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WHAT THIS PAPER ADDS

The PLIANTII study is, to date, one of the largest prospective studies on iliac side branch devices, offering further insight on the E-liac stent graft system for endovascular treatment of common iliac artery aneurysm, either unilaterally or bilaterally, in daily clinical practice. This report presents twelve month data that include patients treated outside the current instructions for use with the E-liac stent graft system. The study demonstrates a twelve month survival rate of 96.7% and technical success rate of 93.1%. These findings substantiate the safety and effective performance of the device, corroborating the promising results of the earlier PLIANT study.

Objective: The aim of this study was to prospectively evaluate the real world outcomes of the E-liac stent graft system used to electively treat common iliac artery aneurysms, either unilaterally or bilaterally.

Methods: PLIANTII is a prospective, observational, non-randomised, multicentre study. The E-liac stent graft system was implanted for the treatment of iliac artery aneurysms in 295 patients across 30 European centres between September 2018 and September 2023, with 236 patients also treated for a concomitant infrarenal abdominal aortic aneurysm. The endpoints, including clinical outcomes, are reported up to the twelve month follow up. The primary endpoint was a composite of freedom from type I or III endoleak plus patency of the external (EIA) and internal iliac arteries (IIA) on the E-liac implantation side(s) at the twelve month follow up. Technical success was defined as successful access and deployment of the stent graft without surgical conversion, death, type I or III endoleak, or graft limb occlusion, assessed at discharge or 30 days. Clinical success, evaluated at twelve months, also included the absence of stent graft infection and iliac aneurysm rupture.

Results: Two hundred and ninetyfive consecutive patients (95.6% male; mean age 72.7 years) were included. The primary endpoint was achieved in 91.8%. No death was recorded within 30 days of implantation, and seven deaths had occurred at twelve months. The Kaplan–Meier estimated survival rate up to the twelve month follow up visit was 96.7 ± 1.2%. Technical success at discharge or 30 days was achieved in 93.1% of patients, while clinical success at twelve months was achieved in 91.2%. There were 5.4% re-interventions within 30 days and 12.9% within twelve months. The Kaplan–Meier estimated freedom from E-liac related re-intervention up to the twelve month follow up visit was 91.3 ± 1.8%. The primary patency rate at discharge or 30 day visit was 97.6% (284/291) for the EIA and 96.2% (280/291) for the IIA, whereas Kaplan–Meier estimated freedom from occlusion up to twelve months was 94.5 ± 1.6% for the EIA and 94.7 ± 1.5% for the IIA.

Conclusion: The one year data from the PLIANTII study show that treatment with the E-liac stent graft system is safe and results in good technical and clinical success rates.

Keywords: E-liac stent graft system, Endovascular iliac aneurysm repair, EVAR, Iliac artery aneurysm, Iliac branch device
Article history: Received 7 August 2024, Accepted 17 February 2025, Available online 20 February 2025

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https://doi.org/10.1016/j.ejvs.2025.02.029

INTRODUCTION

Common iliac artery (CIA) aneurysms have potential for rupture estimated at 3 — 5% per year.[1,2] Approximately 20 — 30% of patients with abdominal aortic aneurysm (AAA) also have unilateral or bilateral CIA aneurysms, further complicating therapeutic decision making.[3] Although the rate of solitary iliac artery aneurysm is low, preservation of internal iliac artery (IIA) blood flow is now recommended, especially in larger CIA aneurysms. Small aneurysms (< 30 mm) rarely rupture, but according to the current guidelines an iliac artery aneurysm with a diameter of ≥ 40 mm should be considered for elective repair.[4]

Based on the European Society for Vascular Surgery (ESVS) AAA guidelines, endovascular aortic aneurysm repair (EVAR) has become widely accepted as a first line treatment, providing reduced peri-operative morbidity, shorter hospital stays, and faster recovery than open surgery.[4] However, covering the IIA carries the risk of buttock claudication for 27.9% of patients, although 48.0% have been found to resolve after 21.8 months.[5]

Different devices are applied for EVAR treatment, and data have been gathered on the risk of using flared legs for anchoring in dilated CIAs.[6] One study noted early complications, including type I and III endoleaks (7%) and device migration (4%), as well as late complications such as limb occlusion (6%) and aneurysm related death (2%). The importance of selecting the appropriate flared limb device for each patient's specific anatomy has been emphasised in order to reduce these risks.[7] Additionally, there are more endoleaks and limb occlusions associated with this technique, necessitating surveillance and potential re-interventions.[8]

The E-liac stent graft system (JOTEC GmbH, Hechingen, Germany) is tailored to address the anatomical challenges of CIA aneurysm, offering improved conformability to the vessel walls, precise deployment, and secure anchoring. This makes it a versatile option for treating unilateral or bilateral aorto-iliac or iliac aneurysms, while providing a safer distal landing zone, thus reducing the risk associated with iliac artery coverage. The first study on the E-liac stent graft system (PLIANT) at twelve months on a much smaller sample size ($n = 45$) demonstrated a high survival rate of 100%, with a 5% device related re-intervention rate.[9] In the current PLIANTII study, 30 centres have prospectively collected real world outcomes from patients with aorto-iliac or iliac aneurysms treated with the E-liac stent graft system, also including those treated outside the instruction for use (IFU). This approach has resulted in a very large patient cohort, thereby enhancing the reliability and applicability of the findings.

The PLIANTII study prospectively evaluates the real world outcome of the E-liac stent graft system in 295 patients with aorto-iliac or iliac aneurysms, with data collected up to the twelve month follow up visit.

METHODS

This study followed the reporting guidelines from the STROBE (Strengthening the Reporting of Observational Studies in Epidemiology) statement for cross sectional studies.[10] The study was conducted according to the Declaration of Helsinki. Where required, the study protocol and patient informed consent form were reviewed and approved by the ethics committees at the participating centres. The PLIANTII study was registered under ClinicalTrials.gov. as NCT03606083. Ethical approval numbers were provided by each local ethics committee responsible for the participating sites across the respective countries.

Study design and patient population

The PLIANTII study is an observational, prospective, non-randomised, multicentre study evaluating the real world outcome of the E-liac stent graft system (JOTEC GmbH). Between September 2018 and September 2023, 423 patients with unilateral or bilateral aorto-iliac or iliac aneurysms were screened at 30 European centres (Fig. 1). The participating centres were in Germany, Switzerland, Italy, the Netherlands, Belgium, the UK, Spain, Poland, and Austria. The study intends to collect data up to five years after device implantation. The inclusion and exclusion criteria of the study have been described previously and are accessible via the ClinicalTrials.gov database.[11] In brief, patients aged 18 — 85 years were eligible and the patient's anatomy had to be suitable for stent graft placement on pre-operative computed tomography angiography (CTA). Patients who were treated outside of the E-liac IFU could also be enrolled. Patients must have had an aorto-iliac or isolated iliac aneurysm, or a unilateral or bilateral iliac aneurysm. Patients with a ruptured iliac aneurysm or those with juxta-, para-, or suprarenal aneurysms were excluded. Enrolment took place after the physician had decided to treat the patient with the E-liac stent graft system and the patient had agreed to participate by signing the informed consent form.

The study cohort was divided into two groups: patients receiving isolated E-liac; and patients receiving E-liac in combination with any endovascular AAA stent graft with a commercially available aorto-bi-E-liac stent graft. The

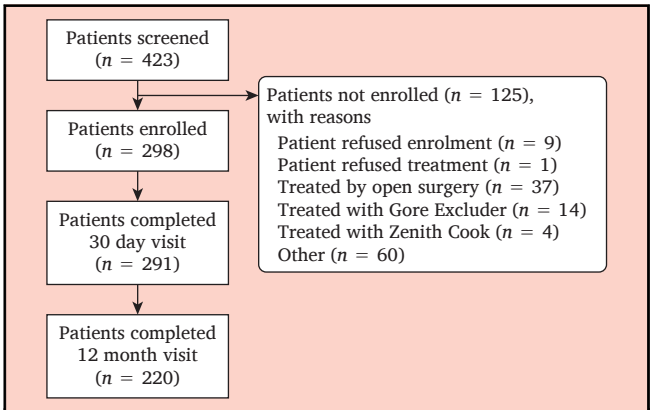

Figure 1. Flowchart of patient enrolment in the study of outcomes of the E-liac stent graft system for treatment of common iliac artery aneurysms.

morphologies of the iliac aneurysms were analysed separately for these patient cohorts. Data were collected according to the PLIANTII protocol at the respective participating hospitals. In this setting, CTA scans were typically performed for pre-operative planning, intervention, at discharge or 30 days, and at the twelve month follow up according to the standard of care. Thus, the actual time points for data collection varied, resulting in 18 patients who had their twelve month follow up visit performed less than nine months (275 days) after the procedure.

Study endpoints and definitions

The primary endpoint was a composite of freedom from type I or III endoleak plus patency of the external iliac artery (EIA) and IIA on the E-liac implantation side(s) at the twelve month follow up. Patency and endoleaks were determined using one of the following imaging methods: CTA, colour duplex ultrasound or contrast enhanced ultrasound (CEUS), echo duplex ultrasound/CEUS with or without native CT, or magnetic resonance angiography (MRA). Imaging was assessed independently at each investigational site. If a suspected endoleak was identified on CT but not confirmed on angiography, follow up was determined at the physician's discretion, including CEUS if contrast was contraindicated.

Secondary endpoints included technical success, clinical success, survival rate, primary and secondary EIA and or IIA patency, endoleak rates, total re-intervention rates, E-liac related re-intervention rates, and changes in aneurysm size (decreasing, stable, or increasing). The aneurysm sac was measured using orthogonal dimensions.

Technical success at discharge or 30 days was defined as successful access and deployment of the stent graft in the absence of surgical conversion, death, type I or III endoleak, and graft limb occlusion.

Clinical success evaluated at twelve months was defined as successful deployment of the stent graft at the intended location without iliac aneurysm related death, type I or III endoleak, stent graft infection, stent graft occlusion, iliac aneurysm rupture, or conversion to open repair.

Data were collected using either CEUS, MRA, or CTA scan at discharge or 30 days and at twelve months.

Operative strategy

A detailed description of the E-liac stent graft system and its implantation procedure has been published previously.[12] Each participating centre followed the established operative strategy outlined in the device instructions for E-liac treatment, while individual surgeons determined the use of anticoagulation and the choice between cutdown or percutaneous techniques. All centres were experienced E-liac users, having had device specific training. Device selection and techniques used to treat the iliac artery aneurysmal disease followed the standard of care and was at the discretion of the operating surgeon.

Statistical analysis

The statistical report was performed on all patients who received the device with no imputation of missing data. Continuous variables were summarised using standard quantitative statistics: number of missing and non-missing observations, mean, standard deviation, median, quartiles, and range (minimum and maximum observed values). Categorical variables were summarised using classical frequency statistics: number of missing and non-missing observations and percentages by categories. Percentages were calculated on the number of non-missing observations. When applicable, bilateral asymptotic or exact confidence intervals (CIs) for binomial distributions were calculated at the 95% level (unadjusted 95% CI). All outcomes were analysed as binary variables. Estimated calculations of survival, freedom from E-liac related re-intervention, and freedom from occlusion were performed using the Kaplan—Meier method, analysed as a time to event variable. Statistical analyses were performed using SAS Version 9.4 (SAS Institute Inc., Cary, NC, USA).

RESULTS

The study enrolled 298 patients at 30 participating centres in Europe. Three patients withdrew their consent leaving 295 patients treated with the E-liac stent graft system. A total of 340 E-liacs were implanted: 194 on the right and 146 on the left side. After implantation, one patient (0.3%) was lost to follow up and three patients (1.0%) did not undergo the follow up visit, but did so at twelve months, resulting in 291 patients (98.6%) with available data for the discharge or 30 day time point. For the twelve month visit, one (0.3%) exclusion criterion was noted, two patients (0.7%) chose not to continue, there were seven deaths (2.4%), and the visit was not performed or had not yet been performed for 61 patients (20.7%). Thus, data were available for 220 patients (74.6%) who underwent the twelve month follow up visit (18 of whom underwent the visit prior to 275 days). Among these, the E-liac was implanted 110 times on the right, 78 times on the left, and 32 times bilaterally.

Of the 295 patients, 282 (95.6%) were male (mean age 72.7 $\pm$ 7.8 years) with a mean body mass index of 28.1 $\pm$ 4.7 kg/m^2 (Table 1). The median maximum diameters of the right and left CIA were both 33 mm. An aneurysm in the IIA with a diameter $\geq$ 12 mm was reported in 56 (29.0%) of 193 patients treated on the right side and 51 (34.9%) of 146 patients treated on the left side. The median maximum diameter of the CIA in patients receiving an isolated E-liac device was 33 mm on the right and 34 mm on the left. Population characteristics and morphology of the iliac aneurysm are detailed in Tables 1 — 3.

Overall, 195 patients (66.1%) were treated with the system outside the IFU for clinical reasons. The criteria for this off label use included at least one of the following: (1) $>50^\circ$ angle between the EIA and CIA; (2) <18 mm thrombus free diameter above the CIA bifurcation; and (3) IIA landing in an anterior or posterior branch of the IIA.

Table 1. Baseline characteristics of patients (n = 295) treated for iliac artery aneurysms with the E-liac stent graft system.

Characteristic	Patients (n = 295)
Male	282 (95.6)
Smoking	
Not or stopped >3 years	150 (50.8)
Stopped ≤3 years	35 (11.9)
Active	92 (31.2)
Unknown	18 (6.1)
Arterial hypertension	219 (74.3)
Diabetes	54 (18.3)
Chronic renal failure	45 (15.3)
Hyperlipidaemia	153 (51.3)
Ischaemic stroke or transient ischaemic attack	26 (8.8)
Ischaemic heart disease	83 (28.2)
Chronic respiratory insufficiency	60 (20.3)

Data are presented as n (%).

Table 2. Iliac aneurysm morphology for all patients treated with the E-liac stent graft system.

Characteristic	Value	n
Right side		
Maximum diameter of CIA − mm	33 (28, 40)	193[*]
Thrombus free diameter above CIA bifurcation − mm	20 (17, 25)	192[*,†]
Diameter of distal landing area in EIA − mm	10 (9, 11.3)	188[*,†]
Diameter of IIA ostium − mm	9 (7, 11)	193[*]
Aneurysm with diameter ≥12 mm in IIA	56 (29.0)	193[*,†]
Left side		
Maximum diameter of CIA − mm	33 (27, 38)	144[†,‡]
Thrombus free diameter above CIA bifurcation − mm	20.5 (17, 26)	140[†,‡]
Diameter of distal landing area in EIA − mm	10 (10, 12)	138[†,‡]
Diameter of IIA ostium − mm	9 (7, 11)	146[‡]
Aneurysm with diameter ≥12 mm in IIA	51 (34.9)	146[‡]

Data are presented as median (interquartile range) or n (%). CIA = common iliac artery; EIA = external iliac artery; IIA = internal iliac artery.
[*] Data were collected from patients who received the device on the right side only (n = 149) and on both sides (n = 45).
[†] Measurements were not available for all patients treated.
[‡] Data were collected from patients who received the device on the left side only (n = 101) and on both sides (n = 45).

A total of 236 patients (80.0%) were treated with an E-liac in combination with an AAA stent graft. The main abdominal devices used in combination were the E-tegra stent graft system (JOTEC GmbH) (76.5%) and Endurant, Endurant II, or Endurant IIs (15%) (Medtronic Inc., Minneapolis, MN, USA). Among these, the E-liac was implanted on the right side in 149 patients (50.5%), on the left side in 101 patients (34.2%), and bilaterally in 45 patients (15.3%).

Discharge or 30 day results

No deaths were recorded at 30 days. Technical success was achieved in 271 (93.1%) of 291 patients at discharge or 30 days (Table 4). Technical success not being achieved was due to six graft limb occlusions; four type Ia endoleaks (two in patients treated with isolated E-liac); nine type Ib endoleaks in the EIA, IIA, or CIA and EIA on the contralateral side (one in a patient treated with an isolated E-liac); three type III endoleaks; and one conversion to open repair. Three patients had two technical failures. In the total patient cohort of 291 patients, there were two type Ib endoleaks in the EIA (0.7%) and five in the IIA (1.7%). Furthermore, type II and type III endoleaks were observed in 65 (22.3%) and three (1.0%) of 291 cases, respectively.

The primary patency rate at discharge or 30 day visit was 97.6% (284/291) for the EIA and 96.2% (280/291) for the IIA. Within 30 days, 16 patients (5.4%) had undergone 17 re-

Table 3. Iliac aneurysm morphology in subgroups of patients treated with an isolated E-liac stent graft system or E-liac in combination with an abdominal aortic aneurysm (AAA) stent graft.

Characteristic	Isolated E-liac		E-liac + AAA	
	Value	n	Value	n
Right side				
Maximum diameter of CIA − mm	33 (28, 42)	33[*,†]	33 (28, 40)	160[§]
Diameter of distal landing area in EIA − mm	10 (9, 12)	33[*,†]	10 (9, 11)	155[§,†]
Length of distal landing area of 15 mm in EIA and CIA	33 (100)	33[*,†]	156 (97.5)	160[§]
Left side				
Maximum diameter of CIA − mm	34 (22, 35)	25[‡]	33 (27.3, 39)	119[‖,†]
Diameter of distal landing area in EIA − mm	9 (7, 10)	25[‡]	10 (10, 11)	113[‖,†]
Length of distal landing area of 15 mm in EIA and CIA	25 (96.2)	26[‡]	118 (98.3)	120[‖]

Data are presented as median (interquartile range) or n (%). AAA = abdominal aortic aneurysm; CIA = common iliac artery; EIA = external iliac artery.
[*] Data were collected from patients who received E-liac on the right side only and on both sides.
[†] Measurements were not available for all patients treated.
[‡] Data were collected from patients who received E-liac on the left side only and on both sides.
[§] Data were collected from patients who received E-liac + AAA on the right side only and on both sides.
[‖] Data were collected from patients who received E-liac + AAA on the left side only and on both sides.

Table 4. Primary and secondary outcomes during follow up of patients treated for iliac artery aneurysm with the E-liac stent graft system.

Outcome	At discharge or 30 days	At 12 months
Primary endpoint	–	202/220 (91.8)
Technical success	271/291 (93.1)	–
Clinical success	–	207/227* (91.2)
Survival rate	291/291 (100)	220/227* (96.9)
Maximum diameter of right CIA compared with pre-operative CT		
Decreased	24/185† (13.0)	42/133† (31.6)
Decreased + stable	184/185† (99.5)	131/133† (98.5)
Increased	1/185† (0.5)	2/133† (1.5)
Maximum diameter of left CIA compared with pre-operative CT		
Decreased	18/136† (13.2)	34/102† (33.3)
Decreased + stable	131/136† (96.3)	101/102† (99.0)
Increased	5/136† (3.6)	1/102† (1.0)
Endoleak		
Isolated E-liac stent graft(s) with type Ia endoleak in the CIA	2/57† (3.5)	0/44† (0.0)
AAA stent graft in combination with E-liac with type Ia endoleak	2/226† (0.9)	1/170† (0.6)
Type Ib endoleak in the EIA	2/291 (0.7)	0/220 (0.0)
Type Ib endoleak in the IIA	5/291 (1.7)	1/220 (0.5)
Type II endoleak	65/291 (22.3)	38/220 (17.3)
Type III endoleak	3/291 (1.0)	4/220 (1.8)

Data are shown as *n/N* (%), where *n* denotes number of patients who achieved the endpoint and *N* refers to the total number of available patients at the time of database transfer. CIA = common iliac artery; CT = computed tomography; AAA = abdominal aortic aneurysm; EIA = external iliac artery; IIA = internal iliac artery.
* *N* = 227 patients denotes the total number of patients reaching twelve month follow up plus the seven patients who died within twelve months.
† Measurements were not available for all patients treated.

interventions, of which the relationship to the E-liac stent graft was assessed as causal in five and unlikely in four patients (Supplementary Table S1). Complications related to the device were limb ischaemia ($n = 2$), limb claudication ($n = 1$), graft occlusion ($n = 2$), thrombosis ($n = 1$), kinking ($n = 1$), buttock claudication ($n = 1$), and bleeding in the groin ($n = 1$).

Twelve month results

The primary endpoint was achieved in 202 (91.8%) of 220 patients at twelve months. Eighteen patients had at least one event of either type I or III endoleak, or occlusion of the EIA and IIA on the E-liac implantation side(s). The clinical success rate at twelve months was 91.2% (207/227). The reasons for clinical success not being achieved were: one death (assessed as causally related to the E-liac stent graft system), one conversion to open surgical repair, 13 graft occlusions, one type Ia endoleak at the proximal landing zone of the AAA stent graft, one type Ib endoleak in the IIA on the E-liac side, and four type III endoleaks (three in the AAA stent graft, one in the E-liac), where one patient had more than one event. Seven deaths were recorded from discharge or 30 days until twelve months. The cause of death was known for five patients, which included sepsis due to myeloid leukaemia, respiratory decompensation, myocardial infarction, cerebral haemorrhage, and heart failure, all non-aneurysm related, whereas one death, with finally lack of respiratory compensation, was related to the E-liac stent graft system implantation. The cause of death for the remaining two patients was not available. The Kaplan–Meier estimated survival rate up to the twelve month follow up visit was 96.7 ± 1.2% (Fig. 2).

The frequency of endoleak in the IIA was type Ib in one (0.5%), type II in 38 (17.3%), and type III in four (1.8%) of 220 patients. The two incidences of type Ib endoleak in the EIA reported at discharge or 30 days resolved: one with an endovascular re-intervention and the other spontaneously. Thus, there was no type Ib endoleak recorded in the EIA at twelve months. In the subgroup of patients treated only with an isolated E-liac, the two patients who had type Ia endoleak recorded at discharge or 30 day follow up received an endovascular re-intervention with the endoleak being resolved. Thus, no type Ia CIA endoleak was observed at twelve months. In the subgroup of patients receiving an AAA stent graft and an E-liac, one patient (0.6%) had a type Ia endoleak.

Overall, 38 patients (12.9%) had a total of 44 re-interventions within twelve months. There were 22 patients with 27 re-interventions reported between 30 days and twelve months, 14 of which were related to the implantation of the E-liac stent graft. Among these, the relationship to E-liac was assessed as causal in five, probable in five, possible in three, and unlikely in one patient (Supplementary Table S1). The Kaplan–Meier estimated freedom from E-liac related re-intervention was 91.3 ± 1.8%

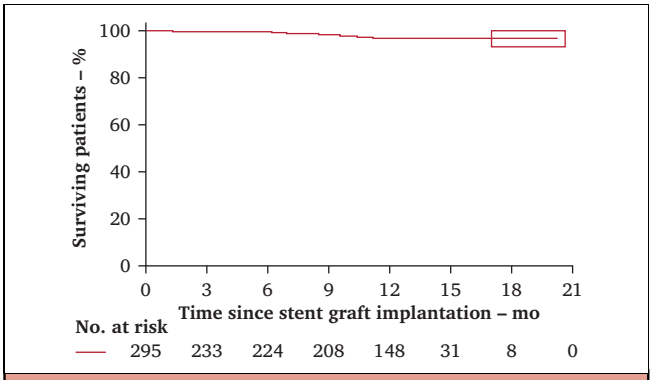

Figure 2. Cumulative Kaplan–Meier estimate of probability of survival after E-liac stent graft implantation for the treatment of iliac artery aneurysm. The red box represents time points where the standard error is ≥10%.

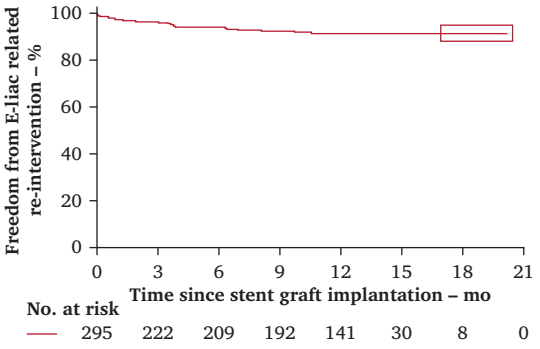

Figure 3. Cumulative Kaplan–Meier estimate of probability of freedom from E-liac related re-intervention after E-liac stent graft implantation for the treatment of iliac artery aneurysm. The red box represents time points where the standard error is ≥ 10%.

(Fig. 3). Details regarding each re-intervention related to the E-liac are shown in Supplementary Table S1. Primary patency, defined as Kaplan–Meier estimated freedom from occlusion up to the twelve month follow up, was 94.5 ± 1.6% for the EIA and 94.7 ± 1.5% for the IIA (Fig. 4).

DISCUSSION

The main findings of this report using the E-liac device were low mortality and low re-intervention rates up to twelve months after the procedure. This is one of the largest prospective studies to date in the management of aorto-iliac or isolated iliac aneurysms using an iliac side branch device, including 295 patients at 30 European vascular centres. A 100% survival at 30 days was achieved, which is in line with previously published data on the E-liac device.[12,13] In early investigational device exemption (IDE) trials, 30 day mortality rates of 1.3%[14] and 3.3%[15] among 92 patients were reported. A later single centre retrospective study on the use of both E-liac stent graft and Cook ZBIS (Cook, Bloomington, IN, USA) reported zero deaths within the 30 day period in patients treated with E-liac and a 2.5% (1/40) 30 day mortality rate for the ZBIS group.[16] The

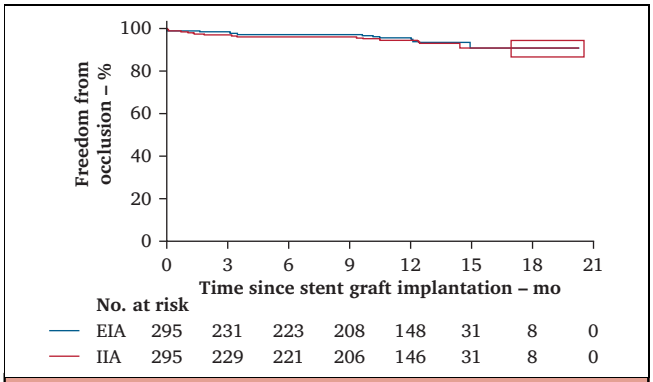

Figure 4. Cumulative Kaplan–Meier estimate of freedom from occlusion in the external iliac artery (EIA) and internal iliac artery (IIA). The red box represents time points where the standard error is ≥ 10%.

present good results conform with those in most prospective iliac branch endoprosthesis (IBE) and iliac branched device (IBD) studies using the Gore (W.L. Gore & Associates, Flagstaff, AZ, USA) and or Cook devices, where the 30 day survival rate was also 100%.[17–19] Thus, there seems to be a positive trend with lower mortality rates in recent years, even though patients with iliac aneurysms have been reported to have a higher risk of death over time.[4,20]

The 93% technical success at discharge or 30 days in the PLIANTII registry is high. There is no clearcut uniform definition of technical success for iliac side branch devices, and the definition differs in each study. However, in other studies reporting on the E-liac stent graft, technical success was in the range of 95 — 100%.[12,13] According to a meta-analysis of 36 studies including 1 502 patients treated with IBDs, the technical success ranged from 97% for both Cook ZBIS and Gore IBE, respectively, to 99% for the E-liac stent graft system.[21] In an IDE trial, the technical success of 87 IBDs deployed in 75 patients was 97%.[14] Thus, the present data are in the same range.

In the present study, the Kaplan–Meier estimated survival rate at twelve months was close to 97%. Of the five known causes of death, none was related to the aneurysm, but one was related to the procedure. The reported one year overall survival rates of either Gore or Cook devices is around 95%.[2,19,22,23] The PLIANT study (conducted prior to PLIANTII and using the E-liac device) also had a 100% survival at twelve months.[9] One early prospective multicentre study with the Cook device reported a lower survival rate of 86.5% within fourteen months,[24] while no death was aneurysm related. No detailed information on patient comorbidities was given in that study.[24] Thus, the survival at one year is high and deaths are rarely related to the aneurysm.

The IIA and EIA patency rates are high. This has been observed for the Dacron devices (Zenith and E-liac) and also the expanded polytetrafluoroethylene (ePTFE) device (Gore IBE). This is exemplified by the fact that the primary and secondary EIA patency rates were close to 95% at twelve months. Likewise, the primary and secondary IIA patency rates at twelve months were higher than 97% in several other studies.[9,23] Some reports have shown lower patency rates down to 84% but the majority have reported higher patency rates.[2,18,25–27] Thus, the patency rates observed for the E-liac device in the PLIANT and PLIANTII studies are comparable with those previously reported with other devices.

The use of a distal branch to anchor the IBD in the hypogastric artery has been a matter of debate. However, it seems that this is possible, with good results reported in the literature,[28] which could be supported by the present study. The sealing is good and the fear of occlusion is less, with a high patency rate of 95% in both arteries.

The aortic aneurysm sac diameters decreased or remained stable in most patients over the twelve month follow up period, indicating adequate exclusion of the aneurysm. This may be important, as studies showing failure of AAA shrinkage after EVAR have suggested an association

with a higher long term mortality rate.[29,30] Another study with the E-liac stent graft system observed stable or decreasing (> 3 mm) CIA aneurysms in 93% of patients after treatment at the twelve month follow up.[9] The present findings confirm these primary results.

With respect to the re-intervention rate in PLIANTII, the overall proportion of patients with at least one re-intervention recorded at twelve months follow up was 12.9%, and the freedom from E-liac related re-intervention was 91.3%. The complications of either graft occlusion, type Ia, Ib, Ic, II, and III endoleaks, limb ischaemia, graft stenosis, or graft thrombosis resulted in re-interventions resolving the symptoms (Supplementary Table S1). Specifically, nine cases of endoleak were resolved following endovascular re-intervention. The present E-liac related re-intervention rate was comparable with the 5% in the PLIANT study.[9] Another recent study on a smaller cohort reported a 2.6% E-liac specific re-intervention rate at one year.[13] Another retrospective single centre study on the Cook device found a re-intervention rate of 2.5% at one year,[31] whereas the corresponding rates in three prospective studies with the same device at the twelve month follow up were around 15%.[26,32,33] For the Gore IBE, two prospective studies reported re-intervention rates in the same range.[15,18] The higher number of re-interventions identified in prospective studies is probably due to the systematic follow up and data collection inherent in this design, which captures more detailed outcomes compared with retrospective studies. This demonstrates the value of a prospective approach, as it provides a more comprehensive assessment of patient outcomes.

The present prospective study is collecting data on one of the largest prospective cohorts with endovascularly treated CIA aneurysms. This is leading to much more robust data and the possibility of detecting changes in subcohorts. As most failures with all endovascular devices for treating aneurysms appear later than twelve months, the differences are expected to be seen later on.

Limitations

Limitations of this prospective registry include its observational, non-randomised design without a control group, the use of the device outside the IFU, as well as the lack of a CoreLab for reviewing the CT scans. Patients were evaluated for treatment based on the opinions of the surgical teams following patient assessment, including treatment with E-liac as well as other iliac side branch devices, or even open surgery in several cases. It should be acknowledged that there is potential for bias in the patient cohort owing to the treatment choice made by the surgeon; however, this is an inherent limitation in all observational studies. An attempt was made to minimise any potential bias by including a large number of participating hospitals located in several different countries. Despite this, considering that the PLIANTII study was primarily undertaken in European hospitals, there may be potential issues with the generalisability of the results. Therefore, long term follow up results in more countries are required to confirm the findings of this registry.

Conclusion

The endpoints comparable with other IBD studies as well as the good technical and clinical success rates demonstrate the effectiveness of the E-liac stent graft system in the management of aorto-iliac or iliac aneurysms. Long term results are needed to confirm the efficacy and durability.

CONFLICTS OF INTEREST

A. Oberhuber, O. Richter, V. Makaloski, P. Szopinski, and R. Tines are consultants for Artivion, Inc.

FUNDING

The PLIANTII study was funded by JOTEC GmbH, a wholly owned subsidiary of Artivion, Inc.

APPENDIX A. SUPPLEMENTARY DATA

Supplementary data to this article can be found online at https://doi.org/10.1016/j.ejvs.2025.02.029.

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