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Original Article

Postimplantation syndrome after endovascular aortic repair: Impact of endograft material and a review of the literature

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Abstract

Aim: Postimplantation syndrome (PIS) is a systemic inflammatory response occurring acutely after endovascular aneurysm repair (EVAR), with reported incidence ranging from 14% to 60%. This study aimed to evaluate the association of different endograft materials with the manifestation and severity of PIS and the role of thrombus formation with type II endoleak incidence.

Material and Methods: A retrospective analysis was performed on data from patients who underwent elective EVAR between January 2021 and January 2024. After applying inclusion and exclusion criteria, 171 patients were included. The patients had a mean age of 70.3±8.6 years and 93% were male. Patients were divided into PIS and Non-PIS groups, with a subgroup analysis within the PIS group comparing polyester and expanded polytetrafluoroethylene (e-PTFE) materials. Patient outcomes post-discharge and within the first-year post-surgery were evaluated.

Results: No early mortality was observed. PIS was diagnosed in 39.2% of the patients. There was no significant difference on longer intensive care unit (ICU) or hospital stays among the PIS and Non-PIS groups. The incidence of PIS was significantly higher in the polyester subgroup (60%) compared to the ePTFE subgroup (25%). Univariate logistic regression identified polyester material as the factor associated with PIS (P=0.03). First-year computed tomographic angiography (CTA) follow-ups showed a statistically significant lower incidence of type II endoleak (p=0.01) and higher new thrombus formation (p=0.04) in the polyester group.

Conclusion: Following EVAR, the patients experience systemic inflammatory responses influenced by the choice of endograft material. Polyester endografts are associated with a higher incidence of PIS and thrombogenicity but a lower incidence of type II endoleak in our study.

Keywords: Endovascular aneurysm repair, postimplantation syndrome

INTRODUCTION

After endovascular aneurysm repair (EVAR) is the first-line treatment for anatomically suitable infrarenal abdominal aortic aneurysms (iAAA). The main reason is the less invasiveness of the procedure and the early successful outcomes compared to open surgical repair (OSR).

OSR for iAAA represents a high-risk surgical procedure associated with hormonal and metabolic stress due to the systemic inflammatory response (SIR) triggered by aortic cross-clamping and surgical trauma. On the other hand, EVAR involves smaller incisions and reduces the amount of tissue manipulation required compared to traditional surgical approaches. Nevertheless, intraluminal manipulation of thrombus using catheters and devices, as well as deploying endografts made of nitinol with polyester or expanded polytetrafluoroethylene (e-PTFE) materials, may also lead to a type of SIR known clinically as postimplantation syndrome (PIS). The underlying mechanisms may differ; however, both treatment modalities have similar SIRs in various levels of severity [1]. Velasquez first described this phenomenon in 1999 [2].

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PIS denotes an acute-phase SIR after EVAR. The reported incidence of PIS varies considerably in the early postoperative period, ranging from 14% to 60% in the literature [3-13]. The pathophysiological mechanisms contributing to PIS remain incompletely elucidated. Speculation exists regarding potential influences such as the type of stent graft utilized or mural thrombus within the AAA in modulating this inflammatory response.

Although generally well tolerated, PIS may contribute to a more complex postoperative recovery phase, potentially necessitating prolonged hospitalization. Consequently, it could be categorized as a procedural complication. Voûte et al. [7] identified polyester stent grafts as independently associated with a heightened risk of PIS, a finding corroborated by Moulakakis et al. [8] in subsequent research. Investigations into the association between PIS and patient outcomes, including cardiovascular or other adverse events, revealed that PIS did not influence 30-day or long-term survival [14].

We aimed to explore PIS in our patients with EVAR and to evaluate the predisposing factors on PIS. The clinical outcomes, type II endoleak occurrence, mural thrombus occurrence and blood tests of patients were assessed retrospectively.

MATERIAL AND METHODS

A retrospective analysis was conducted on collected data from patients who underwent standard EVAR between January 2021 and January 2024. The study design and protocol underwent review and approval by the Institutional Review Board (E1-21-1725). Patients with missing data on preoperative, postoperative computed tomography angiography (CTA), blood samples, or body temperature, as well as any previous history of endoprosthesis implantation, presence of recent infection (<7 days), malignancy, systemic inflammatory conditions, autoimmune disease, patients using chemotherapeutic agents, anti-inflammatory drugs, immunosuppressants or anticoagulants and emergency patients were excluded from the study. Following the application of the inclusion and exclusion criteria, a total of 171 patients remained eligible for inclusion in the present study.

PIS was described as leukocytosis (white blood cell count (WBC) >12x10^9/L), persistent fever (body temperature >37.5°C), and elevated high-sensitivity C-reactive protein (hs-CRP), with negative results from blood cultures.

Two groups were created as the PIS group and the non-PIS group. Body temperature was monitored regularly, and blood samples were collected daily. The imaging protocol included CTA before surgery and in the first postoperative year. Pre-existing and newly formed mural thrombus volumes were quantified using a semi-automated approach.

Surgical Technique: The same cardiovascular surgeon team used surgical techniques for all endovascular procedures. The procedures were all performed under general anesthesia. Both femoral arteries were surgically prepared. All patients received antibiotic prophylaxis. A 7F sheath was placed in the contralateral femoral artery for pigtail catheterization. Following the administration of 70 units/kg of systemic heparin, the pigtail catheter was subsequently inserted and parked between the level of the first and second lumbar vertebra. After the endograft deployment, the procedure was terminated with complementary angiography. The procedure was considered technically successful if there was no type I and type III endoleak on angiography. There were two abdominal aortic stent-graft devices used: Endurant™ II (Medtronic Inc, Santa Rosa, CA, USA) with Polyester material and Lifetech Ankura abdominal endograft (Lifetech, Shenzhen, China) with e-PTFE material. An analysis was conducted comparing devices lined with polyester and e-PTFE. We used 75 polyester endografts and 96 e-PTFE endografts.

Follow-up Procedure: Blood samples were controlled during the first month of outpatient clinic visits. Before discharge, procalcitonin levels and blood cultures were also taken for differential diagnosis of infection, and non-steroid anti-inflammatory drugs were given for treatment. Mainly, colored doppler ultrasound (CDUS) was the primary tool for all patients performed at the first, sixth month and the first postoperative year for all patients [15]. CTA was performed within the first or sixth month according to CDUS and at the end of the first year for all patients except renal impairment for this study.

Primary and Secondary Endpoints: The primary endpoint was to determine the incidence of PIS in EVAR patients and the rates of PIS seen among different endografts. Also, mortality, morbidity and major adverse cardiovascular events (MACE) rates of the groups, ICU period and length of hospital stay (LOS) and blood test results were evaluated. Secondary endpoint was the thrombus formation rate and incidence of type II endoleaks at the postoperative first-year CTAs.

Statistical Analysis

Categorical variables were presented as percentages (%) and compared using the chi-squared test. Continuous variables were expressed as mean±standard deviation (SD) and compared using the Mann-Whitney U test or student-t test. A univariate logistic regression analysis was performed to investigate factors associated with PIS that were defined in the method. Statistical significance was defined as $P<0.05$ and the borders of confidence intervals (95%) were given. Data analyses were conducted using statistical software (SPSS version 25.0, IBM Corp.).

RESULTS

Our study included 171 patients who underwent EVAR between January 2021 and January 2024. The mean age of the patients was

70.3±8.6 years, with a predominant male representation (n=159, 93%). Patients with PIS were identified based on the criteria outlined in the methods section. A total of 67 patients (39.2%) developed PIS. Table 1 demonstrates the demographics of both groups. No notable differences were observed in demographics, risk factors, aneurysm anatomy, or operative details.

Table 1. Preoperative data of PIS and Non-PIS groups

	PIS (n)	Non-PIS (n)	Total (n)	p
Number of patients	67 (39.2%)	104 (60.8%)	171	
Age	72.3±7.6	69.01±9.08	70.3±8.6	0.16
Male	64 (95%)	95 (91%)	159 (93%)	0.36
Hypertension	34 (53.4%)	57 (52.8%)	91 (53.2%)	0.603
Diabetes mellitus	14 (20.9%)	21 (20.2%)	35 (20.5%)	0.911
Chronic obstructive pulmonary disease	24 (35.8%)	43(41.3%)	67 (39.2%)	0.47
Hypercholesterolemia	27 (40.3%)	42 (40.4%)	69 (40.3%)	0.991
Coronary artery disease	35 (52.2%)	56 (53.8%)	91 (53.2%)	0.837
Chronic renal failure	7 (10.4%)	12(11.5%)	19 (11.1%)	0.824
Peripheral vascular disease	4 (5.9%)	5(4.8%)	9 (5.2%)	0.738
Smoking	39 (58.2%)	63 (60.6%)	102 (59.6%)	0.758

Patients with PIS exhibited significantly higher alterations in inflammation markers, such as hs-CRP and WBC count, than those in the non-PIS group (p=0.001). Early mortality and morbidity rates did not differ between groups. PIS was not associated with a longer ICU or hospitalization period (Table 2).

Table 2. Post operative outcomes of PIS and Non-PIS patients groups

	PIS (n)	Non-PIS (n)	Total (n)	P
	67 (39.2%)	104 (60.8%)	171	
C-reactive protein (mg/L)	51.47±33.1	38.77±26.5	47.13±29.47	0.001
WBC count (x10⁹/L)	15.87±3.99	13.5±3.81	14.9±3.9	0.001
Mortality	0	0		1
MACE	2	2		0.64
ICU period (hours)	3.5±2.8	3.1±2.2	3.26±2.45	0.299
Length of stay (mean) (days)	4.5±2.9	3.9±2.4	4.14±2.6	0.44

WBC: white blood cell, MACE: major adverse cardiovascular events, ICU: intensive care unit, CTA: computed tomographic angiography

There were two main endografts, one of which used polyester material and the other e-PTFE material. The incidence of PIS in the polyester subgroup was 60%, which was markedly higher compared to 23% in the ePTFE subgroup (p=0.001). For PIS, endograft types influenced CRP levels (p=0.03) and polyester endografts were statistically significantly higher in quantity and severity than the e-PTFE group (Figure 1). Table 3 demonstrates the differences between subgroups. There was no difference in LOS and ICU period between these two groups (Table 3). We found that the PIS-experienced patients had statistically significantly higher mural thrombus in the first-year CTA controls (p=0.04) and there was a marked difference in the type II endoleak rate in the advantage of the polyester group. Type II Endoleak was relatively low, reaching statistical significance for the polyester group (p=0.01).

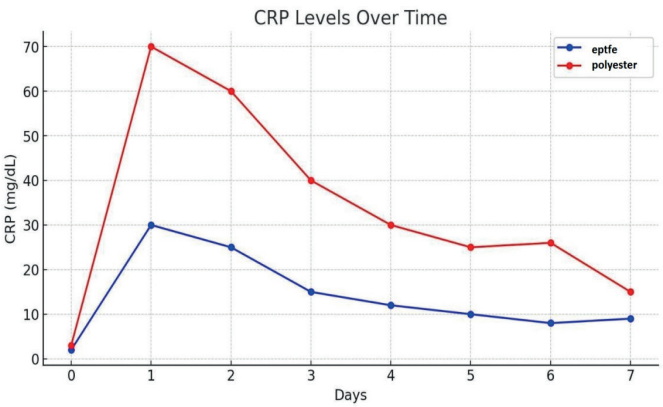

Figure 1. The distribution of PIS among the Polyester and e-PTFE group

Table 3. Postoperative outcomes of patients experiencing PIS according to endograft materials

	Polyester group (n=75)	e-PTFE group (n=96)	p
PIS	45 (60%)	22 (23%)	0.001
WBC count (x10⁹/L)	14.6±3.5	15.2±4.3	0.11
Fever (°C)	37.8	37.6	0.48
C-reactive protein (mg/L)	78±13.5	23±8.5	0.03
ICU period (hours)	3.1±1.5	2.9±1.8	0.44
Length of stay (mean) (days)	4.3±2.1	3.6±1.7	0.089
Mural thrombus volume (ml) at the first year CTA	105.7±9.3	63.4±7.9	0.04
Type II endoleak at the first year CTA (patient)	1 (3.3%)	7 (18.9%)	0.01

PIS: postimplantation syndrome, WBC: white blood cell, ICU: intensive care unit, CTA: computed tomographic angiography

In the univariate regression analysis performed on factors potentially influencing PIS, polyester material appears to be the only significant factor associated with PIS causality (P=0.03). No statistically significant disparities were identified based on the occurrence of PIS (Table 4).

Table 4. Univariate logistic regression analysis of factors that may be associated with PIS

Factors	N or mean±Sd	OR	CI 95%	p
Age	72.3±7.6	1.014	0.97-1.05	0.48
Male	64	0.844	0.24-2.89	0.78
Polyester	45	2.5	1.5-4	0.003
Dm	14	4.42	0.87-22.54	0.07
HT	34	0.27	0.015-5.07	0.06

DM: diabetes mellitus, HT: hypertension

DISCUSSION

Postimplantation syndrome, marked by fever and heightened inflammatory markers, frequently follows EVAR and can lead to extended hospital stays and escalated expenses. The reported prevalence of PIS in the literature ranges from 14% to 60% [3-11]. In our series, 39.2% of the patients were seen in both endograft materials but with different intensities. There was no statistically significant difference between the PIS-experienced and non-PIS groups regarding clinical outcomes, intensive care unit stays, or hospital stays. Patients who had experienced PIS were emotionally anxious about the flu-like discouraging state of health. The polyester material group also had more intensive SIR according to higher CRP levels and had a lower incidence of type II endoleaks in the postoperative first-year CTA controls (p=0.01). The presence of PIS reached statistical significance for the polyester group over e-PTFE (p=0.001).

The type of stent graft material has consistently been associated with PIS, notably polyester grafts, which are linked to a greater risk of PIS than non-polyester stent grafts [7,8,16]. Short-term implications of PIS may include prolonged hospitalization, heightened likelihood of early readmission, and potential escalation in adverse cardiovascular events [7,8,10,14,16]. However, in our series, we did not experience such adverse events. LOS was longer in PIS patients but not statistically significant. Our clinical principle was discharging an uneventful patient mainly after the second or third day of the EVAR procedure after controlling the risk of renal impairment from the blood samples. Therefore, the difference between hospital stays may vary between the centers. In the literature, PIS was responsible for more extended hospital stays and economic burdens. In the literature, there are studies evaluating the impact of endograft materials on PIS after EVAR [7]. A newly released systematic review suggested polyester grafts are strongly associated with PIS compared to PTFE. [12]. We have obtained consistent findings, and in univariate logistic regression analysis, polyester material emerged as the sole factor significantly linked to PIS. (P=0.03). PIS is a relatively common occurrence and warrants consideration in patients who develop a fever following EVAR. The choice of endograft material had a pivotal role in forming PIS, based on the higher incidence of PIS in patients using woven polyester. Finally, polyester endografts have the advantage of statistically significant low type II endoleak rate (p=0.01) in the first year CTA controls, probably due to higher PIS and thrombogenicity of the endograft material.

Kwon et al. [17] reported comparable long-term overall survival rates and other clinical outcomes among patients with and without PIS. Consistent with these findings, our study revealed no discernible link between the onset of PIS and the occurrence of MACE. Moreover, we did not identify any significant correlation between PIS and the incidence of early major complications. Nevertheless, PIS may extend the postoperative hospitalization period, leading to notable economic and administrative considerations. However, this effect did not reach statistical significance in the present study.

Ferreira et al. revealed the long-term outcomes of PIS, with a mean follow-up of 6.4 years and observed no significant disparity in cardiovascular events between patients with and without PIS. Non-PIS patients demonstrated a notably elevated incidence of type II endoleak (28% vs. 9%, p=0.005). Sac dynamics showed no discernible difference between the two groups. Our study also found lower type II endoleak incidence with the polyester PIS group, which had a more intense inflammatory response according to CRP values (Figure 1). Early MACE did not exhibit a higher occurrence in PIS patients; nevertheless, our series recorded only two instances of MACE. Ferreira et al. [15] indicated that PIS did not show an increased risk of cardiovascular events and had no discernible effect on mortality. In their investigation, PIS patients exhibited a lower prevalence of type II endoleaks, mirroring our findings. Furthermore, investigating the correlation between inflammatory mediators linked to PIS and the incidence of mortality and cardiac complications could enhance our understanding of associated risks, potentially leading to strategies for mitigating harm in patients affected by PIS.

Chimney EVAR (chEVAR), branched and fenestrated EVAR (b/fEVAR), and iliac branch devices entail extended and intricate procedures characterized by significant manipulation of vessels. In these cases, issues such as larger area or volume of implanted stent graft material and more acute thrombus formation following implantation are rarely reported in the literature as being related to PIS. Ribeiro et al. reported that advanced EVAR procedures were found to have an elevated risk of developing PIS in contrast to standard infrarenal repair. Moreover, postimplantation syndrome in chEVAR cases generally presents a benign course with negligible influence on perioperative outcomes. [18]. Martinelli et al. [11] validated a reduced occurrence of PIS following endovascular aneurysm sealing (EVAS) using the Nellix (Nellix Endovascular, Palo Alto, CA) in comparison to conventional EVAR techniques. This study emphasizes the role of a newly formed mural thrombus in developing PIS. The lower inflammatory response observed post-EVAS, as opposed to EVAR, may be linked to the endobags incorporated within the Nellix system, which effectively seals the aneurysm sac and mitigates the formation of fresh mural thrombus [11]. Berg et al. compared the risk of PIS following EVAR and EVAS, identifying a tendency toward a reduced occurrence of PIS in the EVAS cohort [19]. Literature suggests that developing a newly formed mural thrombus between the graft and the aortic wall may contribute to the inflammatory response [20]. Our current study found that PIS patients had a statistically significant new onset of thrombus in the first-year CTA controls (p=0.04). The lower type II endoleak incidence in PIS may be due to polyester endografts. The necessity for treatment specific to PIS, targeting the mitigation of the inflammatory response following deployment, remains an unanswered query.

In contemporary literature, there is no standardized protocol regarding the nature and duration of such therapeutic interventions. In their recent survey of vascular surgery departments in Germany, Bischoff et al. [6] revealed that 71% of vascular centers utilized non-steroid anti-inflammatory agents (NSAIDs) to manage PIS. That is also what we do in our practice. In a recently published prospective randomized trial, the Preoperative Methylprednisolone in Endovascular Aortic Repair (POMEVAR), researchers examined the impact of a preoperative single high dose of glucocorticoid (30 mg/kg of methylprednisolone) on PIS. The findings indicated a diminished inflammatory response and accelerated recovery among EVAR-treated patients with anti-inflammatory agents [21]. Nevertheless, the routine administration of medications like steroids or NSAIDs poses significant concerns regarding potential adverse effects, particularly in patients with multiple comorbidities.

The absence of universally accepted diagnostic criteria hampers the consistent reporting of PIS across different centers; additional research is required to delineate the impact of PIS on long-term clinical outcomes and to establish treatment protocols. Subsequent investigations may examine the influence of standardized or symptom-guided anti-inflammatory therapy on the prognosis of patients who develop PIS after EVAR.

We cannot intensely speculate over the endograft choice. However, it seems logical if the patient's preoperative CTA demonstrates a high risk of type II endoleak post-EVAR (patent lumbar arteries (>3) or an inferior mesenteric artery of (>3mm)), a polyester endograft may be a good choice. As a result, systemic inflammatory response syndrome (SIRS) could potentially extend the recovery period and elevate the risk of morbidity in elderly patients with high-risk profiles. Therefore, e-PTFE endografts may be logical for frail patients.

Our study possesses several limitations, including its retrospective and relatively small patient cohort. Additionally, acute-phase proteins such as tumor necrosis factor (TNF) and interleukins were not assessed in this investigation.

CONCLUSION

In conclusion, PIS following EVAR is a prevalent condition. However, it does not seem to have an impact on cardiovascular prognosis. The type of endograft material, mainly polyester, appears to influence this inflammatory process notably. Although

there may be short-term effects of PIS on quality of life, our current study found no disparities in length of hospital stay or clinical outcomes, except for an advantage of low incidence of type II endoleak.

Ethics Committee Approval: The study design and protocol underwent review and approval by the Instutitional Review Board (E1-21-1725).

Patient Consent for Publication: For this retrospective study, informed consent has been obtained in accordance with ethical guidelines.

Data Sharing Statement: The data that support the findings of this study are available from the corresponding author upon reasonable request.

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