



Clinical Research

Driving Technology for Thoracic Endovascular Aortic Repair: An International Analysis of Single-versus Double-Branch RELAY Outcomes

Matti Jubouri,¹ Abdelaziz O. Surkhi,² Mohammed Al-Tawil,² and Gabriele Piffaretti,³ York, UK; Jerusalem, Palestine; Varese, Italy

Background: The introduction of endovascular aortic arch repair (EAR) represents a paradigm shift in the management of complex arch pathologies usually treated with open surgical repair (OSR). This shift in treatment of aortic arch disease has also been accompanied with a rise in commercial interest in EAR resulting in the development of several endografts. However, the RELAY™ Branched by Terumo Aortic can be considered the prime endograft choice. In this international original study, a retrospective comparative analysis of international prospective outcomes data on the single- and double-branch RELAY stent grafts is provided.

Methods: International data on EAR procedures carried out from January 2019 to January 2022 using the single- and double-branch RELAY endograft configurations were collected prospectively. Follow-up data were collected at 30 days, 6 months, 12 months, and 24 months post-operatively. Retrospective descriptive analysis, logistic regression, and Kaplan-Meier analysis were performed.

Results: A total of 125 patients were included, out of which 17 (13.6%) received the single-branch RELAY and 108 the double-branch device. In the single-branch group, no mortalities, strokes, or reinterventions were recorded over 24 months of follow-up. The rates of these outcomes were higher in the other group; however, the differences did not reach significance. Target vessel patency was maintained at 100% throughout the study period with the single-branched RELAY. Overall, our Kaplan-Meier analyses proved that both configurations of RELAY Branched yield excellent short- and mid-term survival and freedom from reintervention.

Conclusions: Our series has clearly demonstrated that EAR using RELAY Branched is a highly efficacious strategy that yields very favorable results which can be considered superior to other EAR devices as well as OSR. Nevertheless, it seems that clinical outcomes with the single-branch RELAY are more optimal than with the double-branch device.

Conflict of interest: None.

Funding sources: None.

Author contributions: Authors MJ, AOS, MT, RC, and LA were involved in the literature search and manuscript writing. MJ and AOS performed the statistical analysis and provided the tables and figures. GP reviewed the manuscript and provided feedback. All authors contributed to the manuscript and approved its final submitted version.

¹Hull York Medical School, University of York, York, UK.

²Faculty of Medicine, Al-Quds University, Jerusalem, Palestine.

³Vascular Surgery, Department of Medicine and Surgery, University of Insubria School of Medicine, Varese, Italy.

Correspondence to: Gabriele Piffaretti, MD, PhD, Vascular Surgery, Department of Medicine and Surgery, University of Insubria School of Medicine, Via F Guicciardini 9, 21100 Varese, Italy; E-mail: gabriele.piffaretti@uninsubria.it

Ann Vasc Surg 2023; ■: 1–12

<https://doi.org/10.1016/j.avsg.2023.02.002>

© 2023 Elsevier Inc. All rights reserved.

Manuscript received: January 7, 2023; manuscript accepted: February 10, 2023; published online: ■ ■ ■

INTRODUCTION

The field of aortovascular surgery has seen a major evolution in the management of thoracic aortic disease over the past few decades, from open surgical repair (OSR), to hybrid modalities combining surgical and interventional techniques, to novel totally endovascular approaches. Hence, this has translated to controversies across the literature debating which of the above is the superior strategy for tackling thoracic aortic aneurysms and dissections. The introduction of thoracic endovascular aortic repair (TEVAR) and, more specifically, endovascular aortic arch repair (EAR), represents a paradigm shift in clinical practice due to its minimally invasive and less physiologically demanding nature, translating into superior clinical outcomes.^{1,2} Although OSR is still considered the gold standard intervention for aortic arch pathology, it has been associated with in-hospital mortality rates of up to 27% and postoperative paraplegia rates as high as 19.6%.^{3,4} As a result, EAR has more recently become an area of great research interest focusing on clinical outcomes including mortality, neurological injury, target vessel patency (TVP), complications such as endoleak and distal stent-graft-induced new entry (dSINE), and reintervention. This original study, therefore, aimed to investigate clinical outcomes achieved with the RELAY™ Branched (Terumo Aortic, Scotland UK) EAR endograft.

This shift in treatment of aortic arch disease has also been accompanied with a rise in commercial interest in TEVAR and EAR resulting in the development of several endografts, examples of which are the aforementioned RELAY Branched (Terumo Aortic, Scotland UK), Cook Zenith™ (Bloomington, IN, USA) and Najuta™ (SB-Kawasumi, Kanagawa, Japan).² This growing commercial interest in EAR has broadened its applicability due to the constant technological advancements in stent grafts, as up to 40% of patients requiring aortic arch repair are deemed unsuitable for OSR.⁵ Out of the commercially available devices for EAR, the RELAY Branched by Terumo Aortic can be considered the most optimal option owing to its unique design features and high versatility, offering a wide range of custom-made device configurations tailored to individual patient anatomy. The design of the precurved inner catheter and dual sheath conforms the alignment with the curvature of the arch and ascending aorta. The main body of the RELAY Branched endograft has radiopaque-marked window(s) situated on the dorsal aspect of the endograft which facilitates the cannulation of one, two, or all three supra-aortic vessels using either a single-,

double-, or triple-branched device, respectively, allowing more precise deployment and, in turn, higher technical success (Fig. 1).²

In this international original study, a comparative analysis of outcomes associated with the single- and double-branch RELAY stent grafts is provided using international multicentre data. Follow-up data on both intraoperative and postoperative outcomes are analysed and compared, including procedural and endovascular times, mortality, strokes, TVP and reintervention, as well as the patient demographics.

MATERIALS AND METHODS

Study Design

The present original study in an international multicentre analysis of EAR procedures using the single- and double-branch RELAY stent-grafts. The procedures were completed between January 2019 and January 2022, and data was collected prospectively and stored in a registry. This was afterwards recovered and analysed retrospectively to compare the clinical outcomes of the single- and double-branch stent-grafts including procedural and endovascular times, mortality, neurological injury, TVP and reintervention, as well as the patient demographics.

Patient Population

During the time frame specified above, the RELAY stent grafts were used to treat a total of 125 patients. Of these, 17 (13.6%) received a single-branch device, and 108 (86.4%) received a double-branch one. This decision was made in a multidisciplinary team manner considering several factors such as the extent of the pathology, individual patient comorbidities, and vessel access. The male to female ratio was 2.8:1 among the 125 patients, with 92 (73.6%) being males and 33 (26.4%) being females. Acute presentations accounted for 47.2% ($n = 59$) of patients, whereas chronic cases accounted for 52.8% ($n = 66$). As for indications, 33 (26.4%) individuals had EAR treatment for an underlying aortic dissection, whereas 92 (73.6%) underwent EAR for an underlying aortic aneurysm.

Follow-up

Following RELAY Branched implantation, each patient was followed-up at predetermined times. After the procedure, patients were followed-up at 30 days, 6 months, 12 months, and 24 months. Parameters measured were disabling strokes (DS) and nondisabling strokes (NDS), TVP, reinterventions, and mortality.



Fig. 1. The three branch configurations of RELAY™ Branched. *Left:* Single Branch RELAY. *Middle:* Double Branch RELAY. *Right:* Triple Branch RELAY. Figure reused from Terumo Aortic website.

Table I. Patient demographics distribution: Single versus double branch RELAY

	Single branch (n)	Double branch (n)	P-value
Mean age (SD)	66.8 (9.3)	70.7 (9.9)	0.122
Urgency			0.311
Acute	6	53	
Chronic	11	55	
Pathology			0.384
Aneurysm	11	81	
Dissection	6	27	
Gender			0.384
Male	11	81	
Female	6	27	

Statistical significance for all two-tailed tests was set at $P < 0.05$.

Statistical Analysis

The data were imported into SPSS 26 for Windows. The results of descriptive analysis were tabulated. The Pearson Chi-squared test was used to investigate relationships between categorical variables. The various *t*-tests were used to assess continuous data that were normally distributed. Nonparametric test Mann-Whitney *U* was employed for variables with non-normal distribution and ordinal data. The associations between outcomes and variables were examined using binary logistic regression. The survival analysis was conducted using Kaplan-Meier and a log-rank *P*-value. The threshold for statistical significance was set at a *P*-value of 0.05.

RESULTS

Patient Demographics

The mean age for patients treated with the single-branch RELAY stent graft was 66.8 years with a standard deviation (SD) of 9.3 years, while the

Table II. Total procedural time and endovascular time: Single versus double branch RELAY

	Single branch	Double branch	P-value
Total procedural time (Mean \pm SD)	187 \pm 73	261.2 \pm 81.6	0.001
Endovascular time (Mean ranks)	39.4	66.7	0.001

Statistical significance for all two-tailed tests was set at $P < 0.05$.

mean age for those receiving the double-branch device was insignificantly different at 70.7 years with SD of 9.9 years ($P = 0.122$). The male to female ratio for the single-branch device group was 1.8:1 and 3:1 in the double-branch group ($P = 0.384$). In the single branched group, 6 (35.3%) patients were admitted acutely and 11 (64.7%) with chronic disease. Meanwhile in the double-branch RELAY group, 53 (49.1%) cases were acute and 55 were chronic (50.9%) ($P = 0.311$). Out of the 17 patients receiving the single-branch, 11 (64.7%) were treated for an aortic aneurysm while the other 6 (35.3%) were treated for aortic dissection. On the other hand in the double-branch device group, 81 (75%) had an aneurysm and 27 (25%) a dissection. However, the difference in indications between the two groups did not reach statistical significance ($P = 0.384$). Table I summarizes the above findings.

Procedural and Endovascular Time

The mean total procedural time for the single-branch RELAY implantation was 187 min with a SD of 73 min. As for the double-branch device, this was 261.2 min with a SD of 82.6 min. The mean difference between the groups here was statistically significant ($P = 0.001$). The calculated endovascular time mean rank for the single-branch

Table III. Postoperative disabling strokes: Single versus double branch RELAY

Follow-up	Single branch (<i>n</i>)	Double branch (<i>n</i>)	<i>P</i> -value
30 days	0	4	0.571
6 months	0	6	0.429
12 months	0	5	0.495
24 months	0	4	0.571

Statistical significance for all two-tailed tests was set at $P < 0.05$.

group was 39.4 and 66.7 in the double-branch group, with the difference in mean ranks being statistically significant ($P = 0.001$). Table II summarizes the procedural and endovascular times for both groups.

Follow-up

Zero DS were recorded in the single-branch RELAY group during the entirety of follow-up. With the double-branch device, 4 cases of DS were recorded in the first 30 days post-TEVAR ($P = 0.571$), 6 DS at 6 months follow-up ($P = 0.429$), 5 DS at 12 months ($P = 0.495$) and 4 DS 24 months ($P = 0.571$). Similarly, zero NDS were recorded with the single-branch RELAY. As for the double-branch RELAY, 3 NDS cases were recorded at each point of follow-up ($P = 0.658$), with 4 cases of NDS noted at 24 months ($P = 0.571$). DS and NDS results are summarized in Tables III and IV.

The TVP remained at 100% in the single-branch device group during the whole study period. As for the double-branch RELAY group, TVP was 100% during the first 30 postoperative days. However, this reduced to 88.8% ($n = 96$) after 6 months, 78.7% ($n = 85$) after 12 months, and to 74% ($n = 80$) after 24 months of follow-up. Yet, the difference between the two groups was not significant at 6 months ($P = 0.175$), but was significant at the 12 and 24 months follow-up points ($P = 0.029$; $P = 0.012$). TVP results are summarized in Table V and illustrated in Figure 2.

As for secondary interventions, none were required following single-branch RELAY implantation. However, this was not the case for the double-branch device group which needed 16 reinterventions at 30 days post-EAR ($P = 0.221$), 11 at 6 months ($P = 0.356$), 12 at 12 months ($P = 0.362$), and 11 at 24 months follow-up ($P = 0.356$). These findings can be found summarized in Table VI and visualized in Figure 3.

Table IV. Postoperative nondisabling strokes: Single versus double branch RELAY

Follow-up	Single branch (<i>n</i>)	Double branch (<i>n</i>)	<i>P</i> -value
30 days	0	3	0.658
6 months	0	3	0.658
12 months	0	3	0.658
24 months	0	4	0.571

Statistical significance for all two-tailed tests was set at $P < 0.05$.

Table V. Postoperative target vessel patency: Single versus double branch RELAY

Follow-up	Single branch	Double branch	<i>P</i> -value
	<i>n</i> (%)	<i>n</i> (%)	
30 days	16 (100%)	108 (100%)	-
6 months	16 (100%)	96 (88.8%)	0.175
12 months	16 (100%)	85 (78.7%)	0.029
24 months	16 (100%)	80 (74%)	0.012

Statistical significance for all two-tailed tests was set at $P < 0.05$.

No mortalities were recorded in the single-branch RELAY group during the full study period. As for the double-branch device group, 4 deaths were reported only during the first 30 days postoperatively, with none reported afterwards ($P = 0.571$). However, these 4 mortalities were not device- or procedure-related. A summary of these results can be found in Table VII.

Subanalysis

We conducted an analysis comparing the procedural time in 3 different groups: single-branch RELAY patients, double-branch RELAY patients who required reintervention, and double-branch RELAY patients without reintervention. The analysis showed that the procedural time was significantly higher in the double-branch RELAY group without reintervention than the single-branch device group ($P = 0.001$). However, the analysis also showed that this difference was not significant between patients in the double branched group who required a reintervention and those who received the single-branch RELAY ($P = 0.232$). Lastly, the results demonstrated that double-branch RELAY patients who required reintervention had a significantly reduced procedural time than counterparts who did not require reintervention ($P = 0.008$). The above results of the analysis are summarized and illustrated in Tables VIII–X and Figures 4–6.

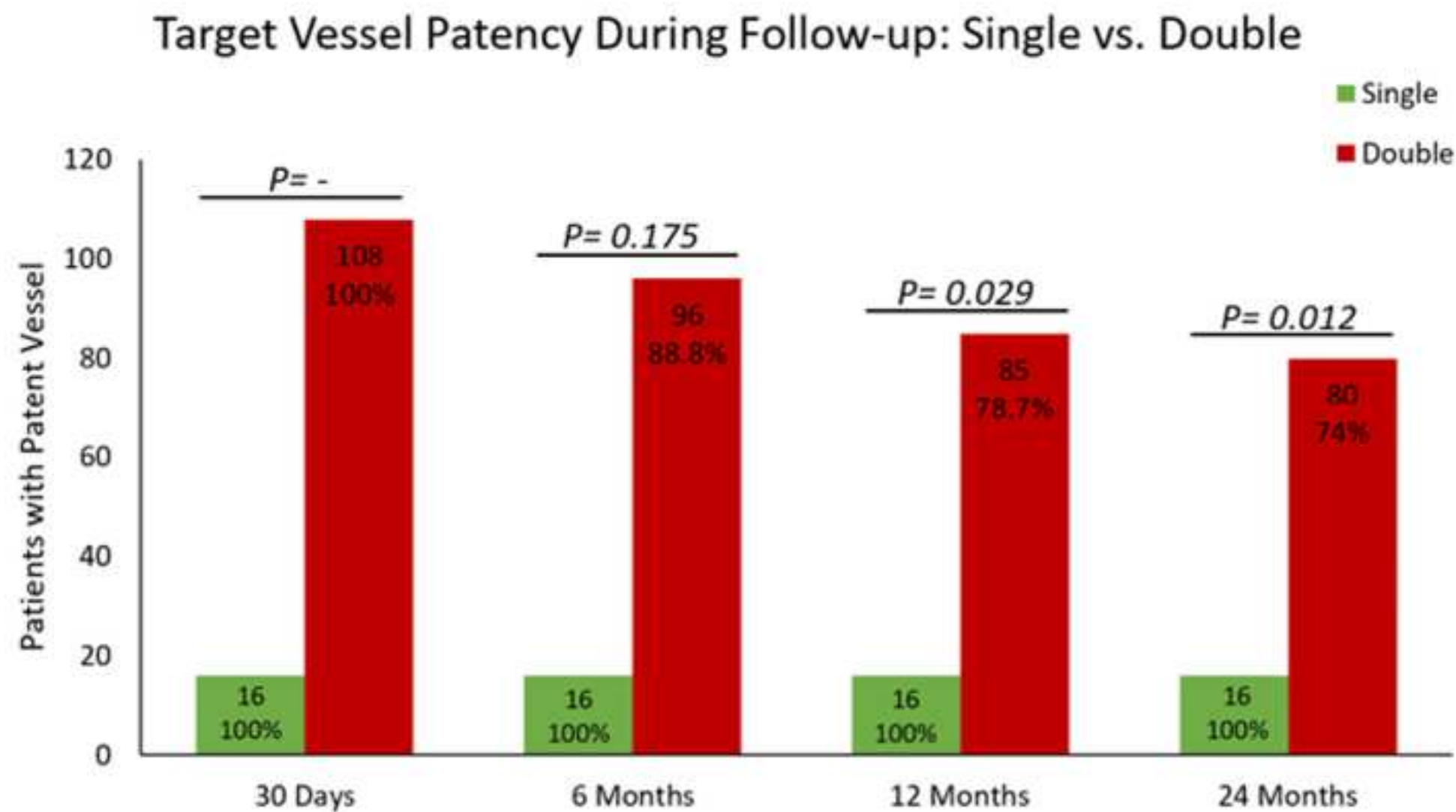


Fig. 2. Target Vessel Patency: Single versus Double Branch.

Table VI. Postoperative reintervention: Single versus double branch RELAY

Follow-up	Single branch (n)	Double branch (n)	P-value
30 days	0	16	0.221
6 months	0	11	0.356
12 months	0	12	0.362
24 months	0	11	0.356

Statistical significance for all two-tailed tests was set at $P < 0.05$.

Logistic Regression

Logistic regression for the study population for TVP at the study end point revealed that gender, age, urgency, pathology, and procedural time did not correlate to TVP. The regression analysis showed, however, that endovascular time directly correlated to TVP (odds ratio [OR] = 1.103, $P = 0.036$). The logistic regression results for TVP are shown in Table XI.

Logistic regression for reintervention at 30 days post-TEVAR revealed that urgency directly correlated with reintervention, which means that patients who presented acutely were more likely to require reintervention (OR = 6.06, $P = 0.007$). The logistic regression results for reintervention are shown in Table XII.

Survival Analysis

A Kaplan-Meier analysis was deployed to study the freedom from reintervention in the single- and double-branch RELAY groups. The analysis

revealed that freedom from reintervention was indifferent between the two groups (log-rank P -value = 0.082) (Fig. 7). Another Kaplan-Meier analysis for the freedom from vessel occlusion showcased that patients treated with a single-branch stent graft were less likely to have an occluded vessel than double-branch device patients (log-rank P -value = 0.021) (Fig. 8). Lastly, freedom from reintervention was linked to urgency. The analysis showed that patients with chronic pathology were less likely to need secondary intervention during the study period (log-rank P -value = 0.002) (Fig. 9).

DISCUSSION

EAR with the RELAY Branched stent graft is associated with highly optimal short- and mid-term postoperative outcomes. Postoperative data associated with the index procedures in the present study are consistent with those documented in literature.^{6–9} Our results show that the single-branch RELAY device configuration is associated with excellent results, namely zero mortalities, zero cases of DS or NDS, maintenance of 100% TVP and no reinterventions required, all across the full 2-year follow-up period. The double-branch RELAY, however, also yielded favorable results. The results between the two groups did not differ significantly with the exception of lower TVP beyond the first postoperative year and longer operative times with the double-branch device. Nevertheless, our series also demonstrates that either RELAY endograft configuration allows for rapid arch repair. Interestingly, the

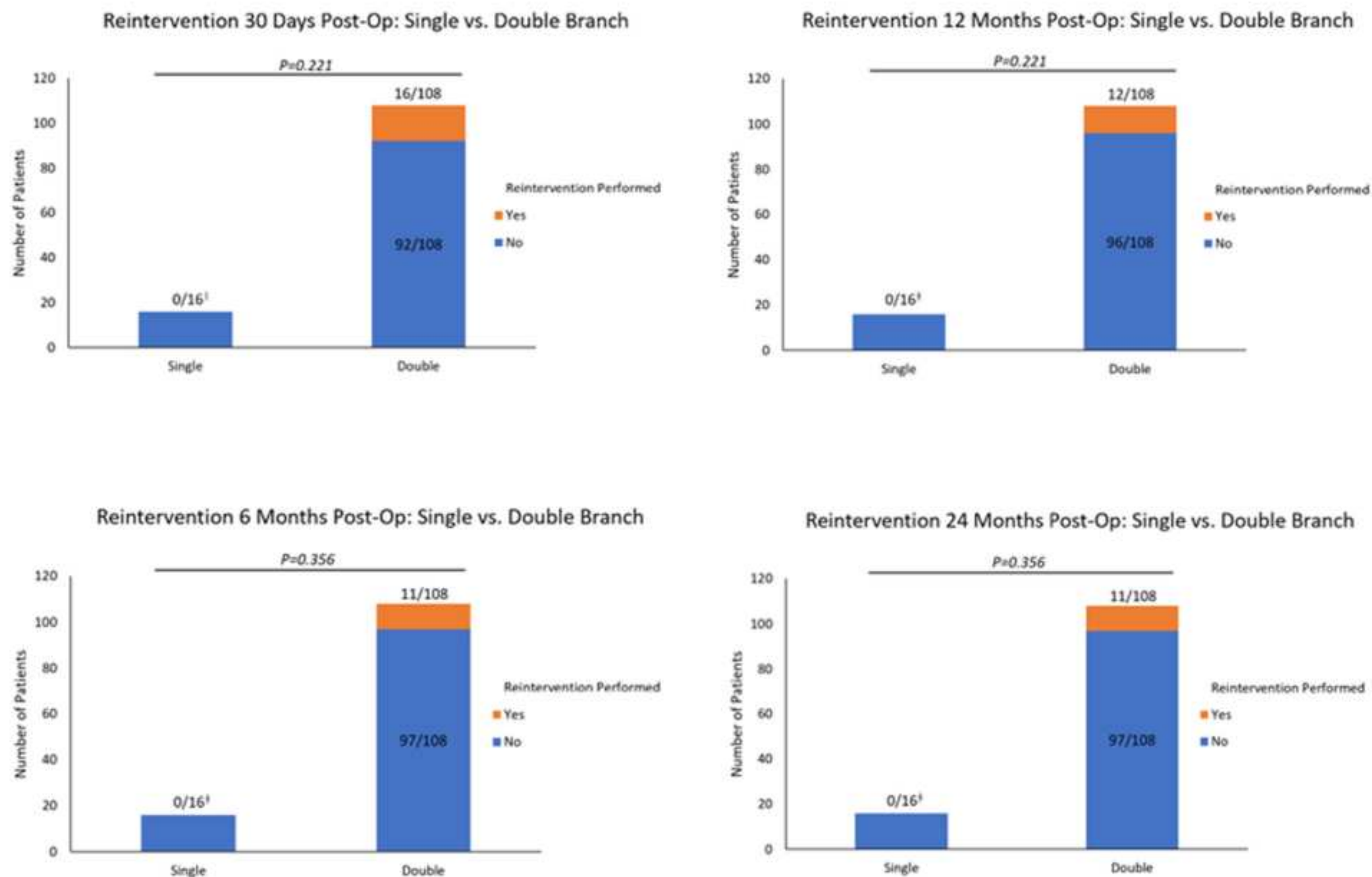


Fig. 3. Reintervention: Single versus Double Branch.

subanalysis conducted demonstrated that double-branch RELAY patients who required reintervention had a significantly reduced procedural time than counterparts who did not require reintervention ($P = 0.008$). In addition, results of the logistic regression analysis associated TVP with endovascular time ($OR = 1.103$, $P = 0.036$). Overall, our Kaplan-Meier analyses proved that both configurations of RELAY Branched yield excellent short- and mid-term survival and freedom from reintervention. It is important to note that the two groups studied were similar at baseline in terms of age, gender, pathology, and urgency.

Only 4 mortalities were recorded in the present studies, all of which were in the double-branch RELAY group but not related to the device itself, and occurred within the first 30 postoperative days, giving an overall mortality rate of 3.05% over 2 years of follow-up. This figure is slightly higher than the 0.67% ($n = 1$) mortality rate reported in Singh et al.⁶ The authors analysed data from 148 patient who received all three branch configurations of the RELAY Branched endograft. However, similar to our results, their single mortality was not related to the procedure itself. In addition,

Table VII. Cumulative death during follow-up periods: Single versus double branch RELAY

Follow-up	Single branch (n)	Double branch (n)	P-value
30 days	0	4	0.571
6 months	0	4	0.571
12 months	0	4	0.571
24 months	0	4	0.571

Statistical significance for all two-tailed tests was set at $P < 0.05$.

analysis conducted by Singh et al.⁶ showed that there was no significant difference in mortality between their three device groups. Our series also did not find a significant difference in mortality between single- and double-branched RELAY patients. The RESTORE⁷ and RESTORE II⁸ clinical trials investigated the efficacy of RELAY Branched in 307 and 173 patients, and reported an overall mortality rate of 7.2% and 6.2% after 2 years of follow-up. Survival following RELAY Branched implantation is superior to that with other EAR/TEVAR devices. For example, a Najuta study with a mean follow-up of 2.9 ± 2.9 years by Sato et al.¹⁰ reported an overall mortality rate of 11.1%.

Table VIII. Mean procedural time: Single branch versus Double branch without reintervention

Follow-up	Single branch without reintervention (mean)	Double branch without reintervention (mean)	P-value
30 days	187	269.2	0.001
6 months	187	266.5	0.001
12 months	187	268.9	0.001
24 months	187	266.7	0.001

Bold: Statistical significance for all two-tailed tests was set at $P < 0.05$.

Table IX. Mean procedural time: Single branch versus double branch with reintervention

Follow-up	Single branch without reintervention (mean)	Double branch with reintervention (mean)	P-value
30 days	187	216.25	0.232
6 months	187	215.4	0.30
12 months	187	200.8	0.527
24 months	187	213.6	0.27

Statistical significance for all two-tailed tests was set at $P < 0.05$.

Table X. Mean procedural time: Double branch RELAY with versus without reintervention

Follow-up	Double branch without reintervention (mean)	Double branch with reintervention (mean)	P-value
30 days	269.2	216.25	0.008
6 months	266.5	215.4	0.035
12 months	268.9	200.8	0.006
24 months	266.7	213.6	0.008

Bold: Statistical significance for all two-tailed tests was set at $P < 0.05$.

Similarly, early mortality with the Cook Zenith reached 18% in O'Callaghan et al.¹¹

Neurological injury is a major factor contributing to mortality and morbidity postoperatively. OSR has traditionally been associated with substantial neurological complication rates, postoperative paraplegia, and stroke rates as high as 19.6% and 11.8%, respectively.³ In comparison, the EAR has been associated with far more favorable neurological outcomes which can be attributed to the absence of the need for circulatory arrest and cerebral perfusion techniques. However, the risk of neurological complications in EAR stems from the manipulation of the supra-aortic vessels, mainly being the left subclavian artery (LSA).¹² Hence, the Society of Vascular Surgery guidelines recommend routine LSA revascularization during elective EAR procedures.¹³ In our series, the overall incidence of DS and NDS was 15.2% ($n = 19$) and 10.4% ($n = 13$). None of the patients receiving the single-branch RELAY suffered any neurological complications,

yet, there was no statistical difference in incidence between both the groups. A recent original study of 148 patients by Tan et al.⁹ focused on neurological outcomes following EAR using the three configurations of RELAY Branched. Their analysis showed that EAR may be associated with much more favorable neurological outcomes compared to OSR. They reported a 4.1% and 5.4% incidence of DS and NDS. The aforementioned RESTORE⁷ and RESTORE II⁸ clinical trials revealed stroke rates of only 1.6% and 0.6% as well as 2 and 2.9% rates of paraplegia using of RELAY Branched, respectively. On the other hand, using Najuta, Sato et al.¹⁰ found a 16.7% and 2.8% rate of stroke and paraplegia. As for Cook Zenith, the aforementioned O'Callaghan et al.¹¹ showed 6% stroke and 6% spinal cord injury postoperatively. This was even higher at 7.4% for each outcomes with Cook Zenith in Spear et al.¹⁴

In terms of TVP, this was maintained at 100% for the entirety of the study period in the single-branch

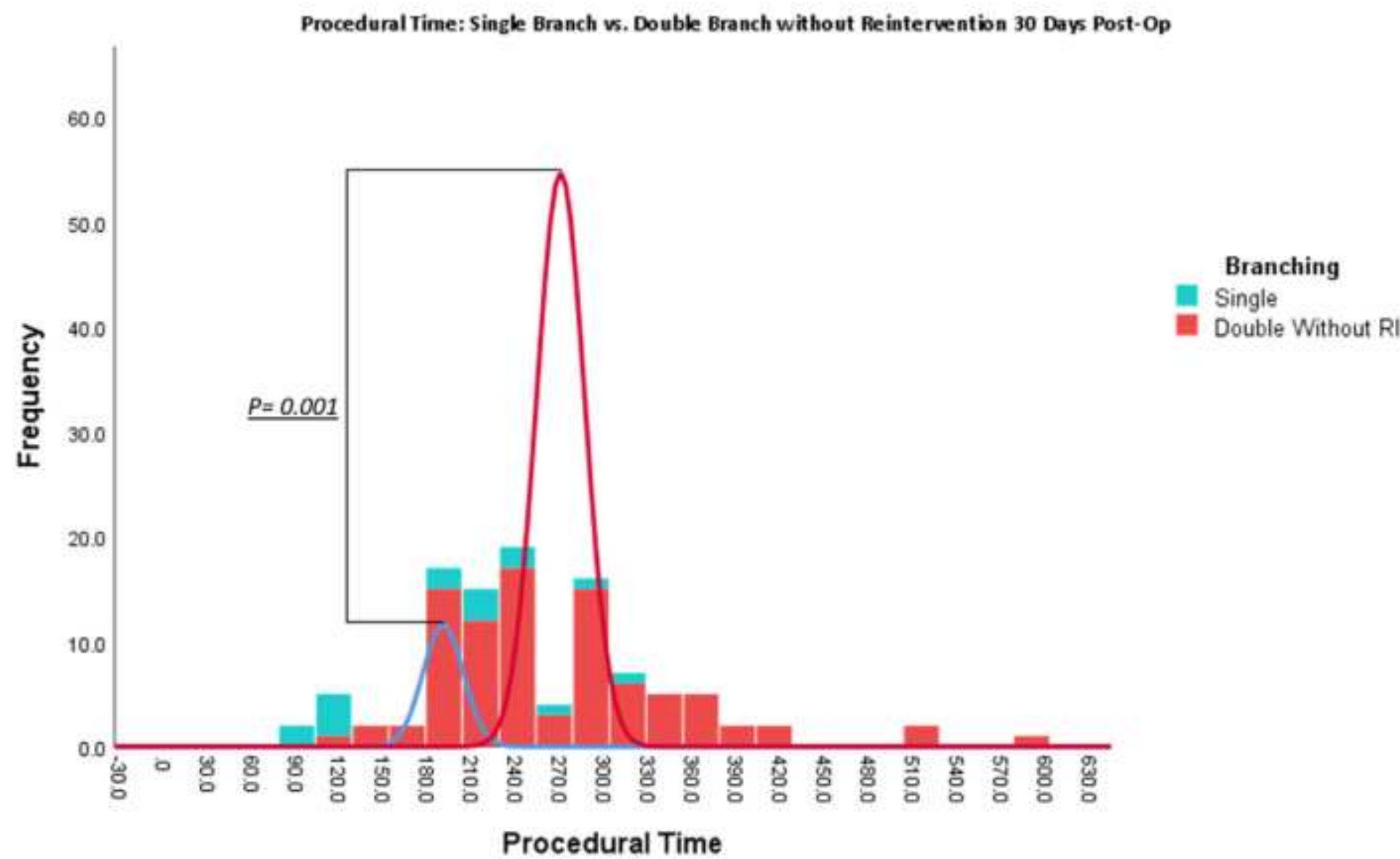


Fig. 4. Procedural Time: Single Branch versus Double Branch without Reintervention.

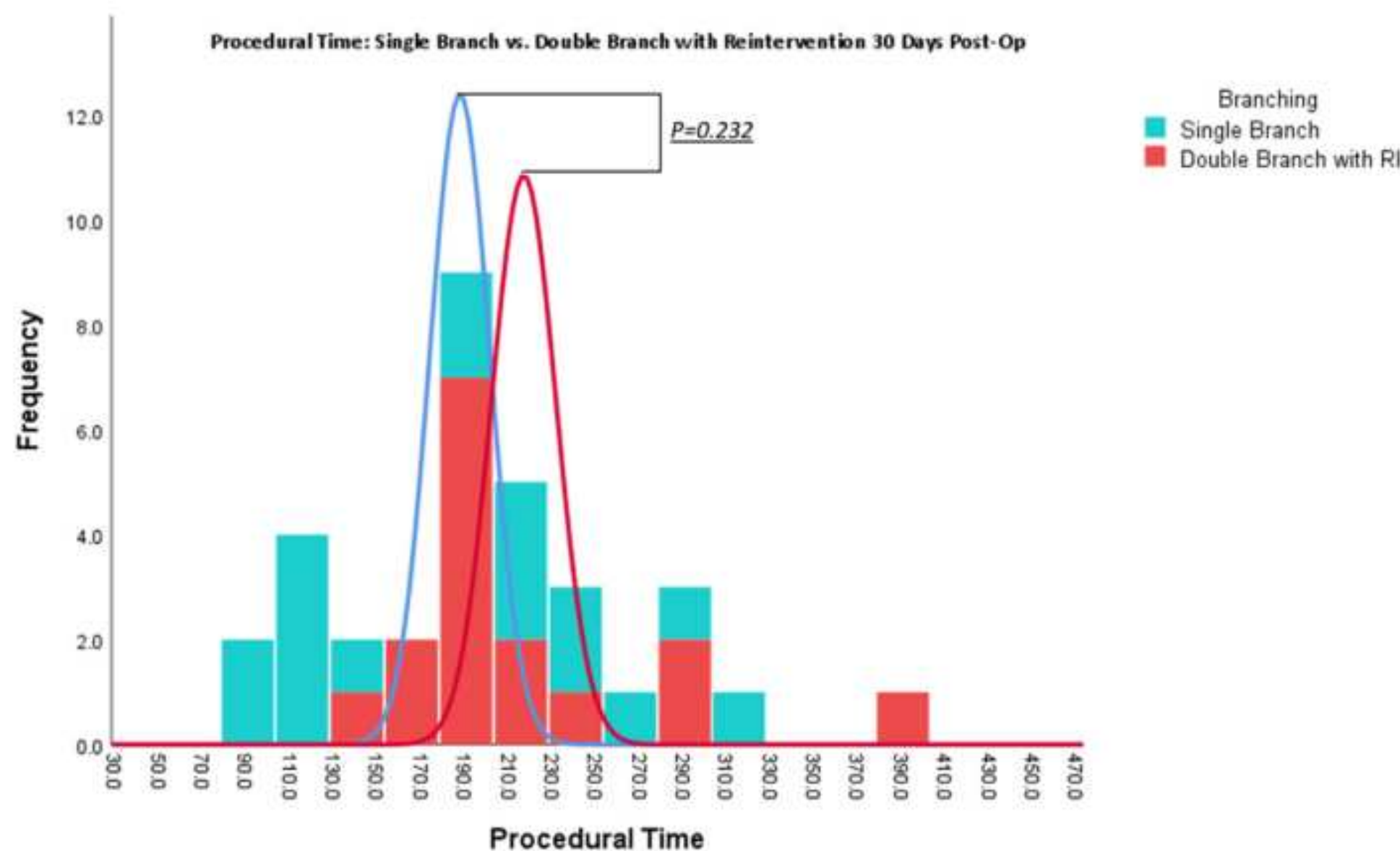


Fig. 5. Procedural Time: Single Branch versus Double Branch with Reintervention.

RELAY group. TVP was 100% at 30 days post-EAR in the double-branch device group, nevertheless, this dropped to 74% by the end of 2-year follow-up. In addition, our regression analysis showed that endovascular time directly correlated to TVP (OR = 1.103, $P = 0.036$), with the double-branch procedures lasting significantly longer ($P = 0.001$). However, TVP was not correlated to any of gender, age, urgency, pathology, and procedural time. Importantly, our results also suggested that patients treated with a single-branch stent-graft were less

likely to have an occluded vessel than double-branch device patients (log-rank P -value = 0.021). Our results are in line with the literature as another original RELAY Branched study also reported 100% TVP in all patients 30 days after receiving the RELAY Branched device. In the same study, 80.2% of patients exhibited TVP at 24 months.⁶

Decline of TVP, in addition to aforementioned complications such as dSINE and endoleak, are significant risk factors for secondary intervention following EAR. In our cohort, no reinterventions

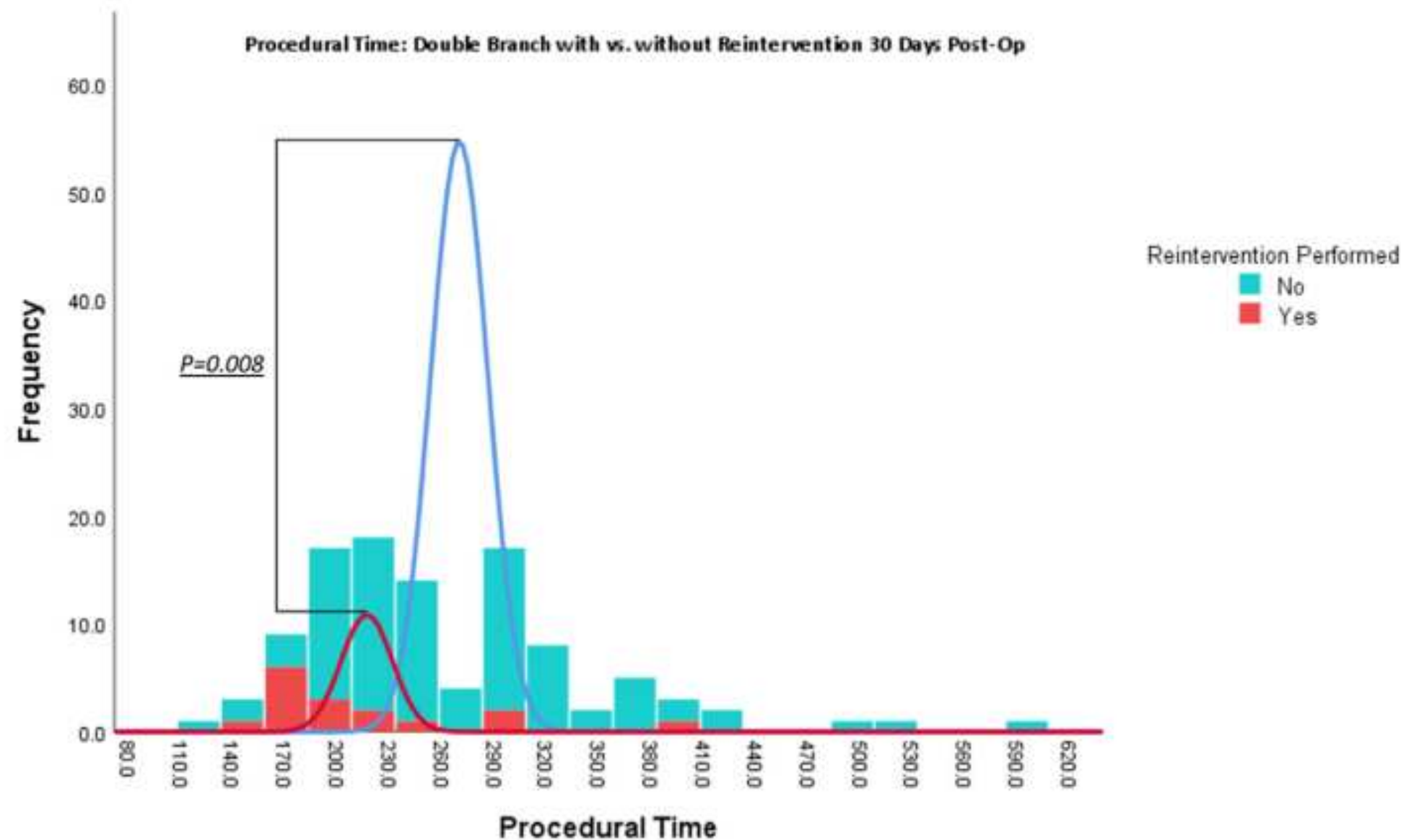


Fig. 6. Procedural Time: Double Branch with versus without Reintervention.

Table XI. Logistic regression of covariates for target vessel patency at study end point

Covariates	Odds ratio	95% CI (lower-upper)	P-value
Gender = Female	1.382	0.423–4.518	0.593
Age	1.020	0.966–1.077	0.479
Urgency = Acute	0.753	0.253–2.247	0.612
Pathology = Aneurysm	0.336	0.070–1.599	0.170
Branching ^a = Single	-	-	0.998
Procedural time	0.998	0.992–1.003	0.392
Endovascular time	1.103	1.007–1.209	0.036

Bold: Statistical significance for all two-tailed tests was set at $P < 0.05$.

CI, confidence interval.

^aNo odds calculated, all cases in the single branch population had a patent vessel.

were required following single-branch RELAY implantation. As for the double-branch endograft patients, 14.8% ($n = 16$) required reintervention during the first 30 postoperative days, with further 34 reinterventions were carried out by 24 months of follow-up. However, as mentioned previously our subanalysis revealed that double-branch RELAY patients who required reintervention had a significantly reduced procedural time than counterparts who did not require reintervention ($P = 0.008$). In addition, logistic regression analysis conducted for reintervention at 30 days revealed that urgency directly correlated with reintervention, with acute patient being at a significantly higher risk of reintervention (OR = 6.06, $P = 0.007$). Similarly, Kaplan-Meier analysis of freedom from reintervention showed that chronic patients were less likely to require reinterventions during follow-up (log-rank P -value = 0.002).

That being said, more patients in the single-branch group presented with chronic disease compared to double-branch one (64.7% vs. 50.9%). The aforementioned Singh et al.⁶ also reported 0% reintervention rate with the single- and triple-branch devices but 16.2% with the double-branch variant. To further verify the RELAY Branched device's superiority, the RESTORE⁷ trial revealed a negligible reintervention rate of 0.7%. In the sequel RESTORE II⁸ trial, early and late reintervention rates were 3.5% and 7.5%. As for Najuta, Sato et al.¹⁰ and Iwakoshi et al.¹⁵ reported 8.3% and 12.5% reintervention rates. Conversely, alarming reintervention rates have been described with Cook Zenith as 7.4% and 30.3% of patients in Spear et al.¹⁴ and O'Callaghan et al.¹¹ required secondary intervention.

The relationship between urgency and outcomes is an important one to consider as shown by our

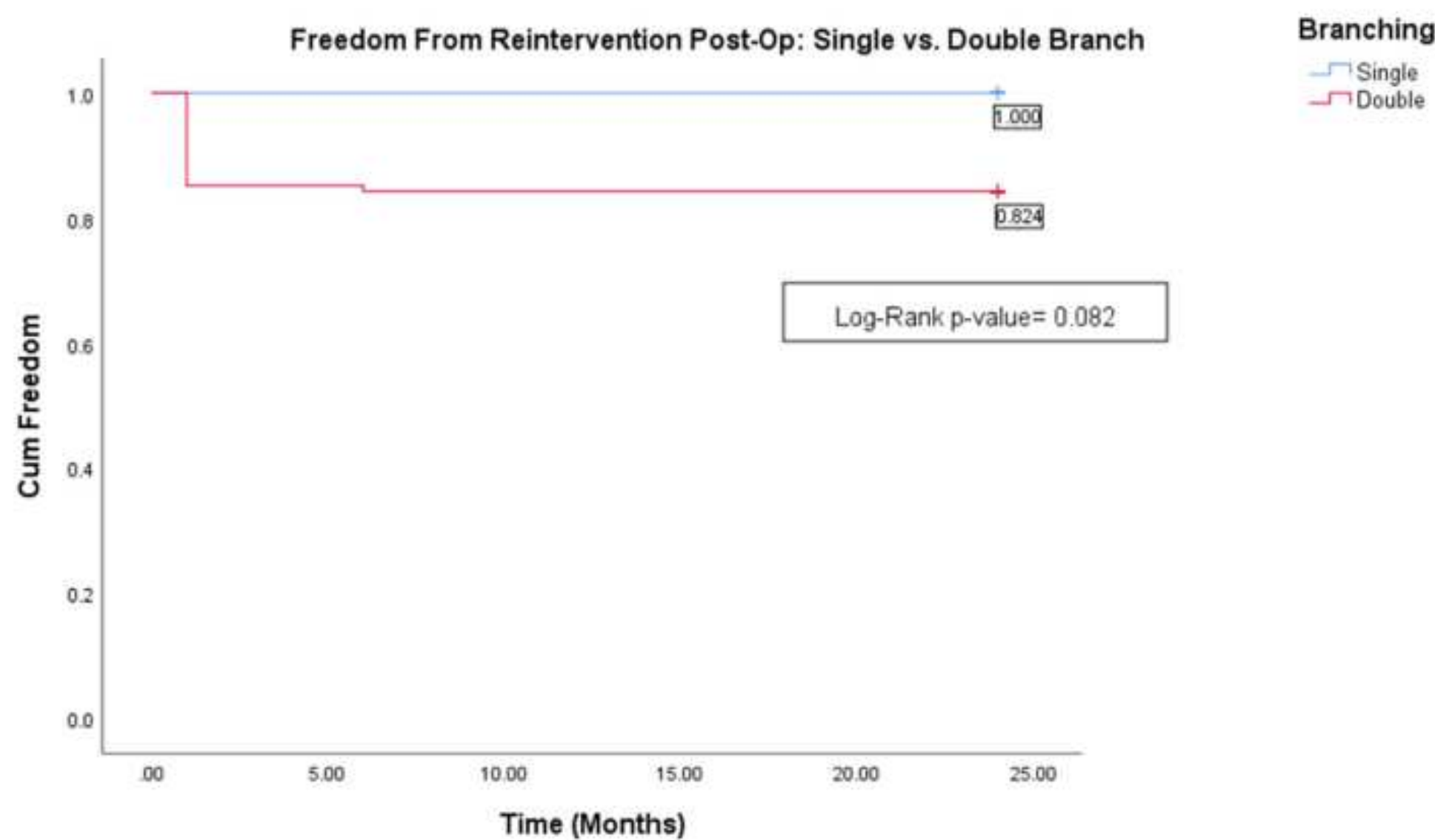
Table XII. Logistic regression of covariates for reintervention 30 days postoperative

Covariates	Odds ratio	95% CI (lower-upper)	P-value
Gender = female	0.629	0.167–2.366	0.492
Age	1.018	0.957–1.083	0.570
Urgency = acute	6.067	1.633–22.538	0.007
Pathology = Aneurysm	1.050	0.313–3.523	0.937
Branching ^a = single	-	-	0.998
Procedural time	0.993	0.985–1.001	0.069
Endovascular time	0.918	0.835–1.009	0.075

Bold: Statistical significance for all two-tailed tests was set at $P < 0.05$.

CI, confidence interval.

^aNo odds calculated, no cases in the single branch population required reintervention.

**Fig. 7.** Kaplan-Meier Freedom from Reintervention: Single versus Double Branch.

results. A recent scoping review of TEVAR in type B aortic dissection (TBAD) also proved that results become poorer as the disease becomes more chronic, with the most optimal outcomes achieved when performing TEVAR in the subacute phase of TBAD.¹⁶ As for the procedural time and endovascular time, while only the latter correlated to TVP in our series, a recent prospective RELAY Branched study reported that endovascular time was associated with a lower risk of reintervention at 30 days, 6 months, and 12 months ($P = 0.011$, $P = 0.019$, $P = 0.037$) and greater TVP at 6 months and 24 months ($P = 0.032$, $P = 0.035$), but no correlation with DS.¹⁷

Given the novelty of EAR, there is a paucity of cost analyses assessing its cost effectiveness compared to OSR. However, a recent review summarized the evidence in the literature regarding the cost effectiveness of TEVAR in TBAD in comparison with OSR

and optimal medical therapy. Despite the higher initial cost of TEVAR, with stentgrafts costing \$12,000–\$19,495, it offers a highly efficacious and long-term cost-effective treatment for TBAD.¹⁸ Hence, it can be drawn that cost-benefit profile of EAR is optimal. That being said, large studies investigating the cost effectiveness of EAR in comparison with OSR are definitely required.

LIMITATIONS

Limitations of the present study include possible inflation bias due to the disproportionately larger double-branch RELAY group ($n = 108$) relative to the single-branch counterparts ($n = 17$). As a retrospective analysis of prospective data, the patients included in this study were also not randomized to

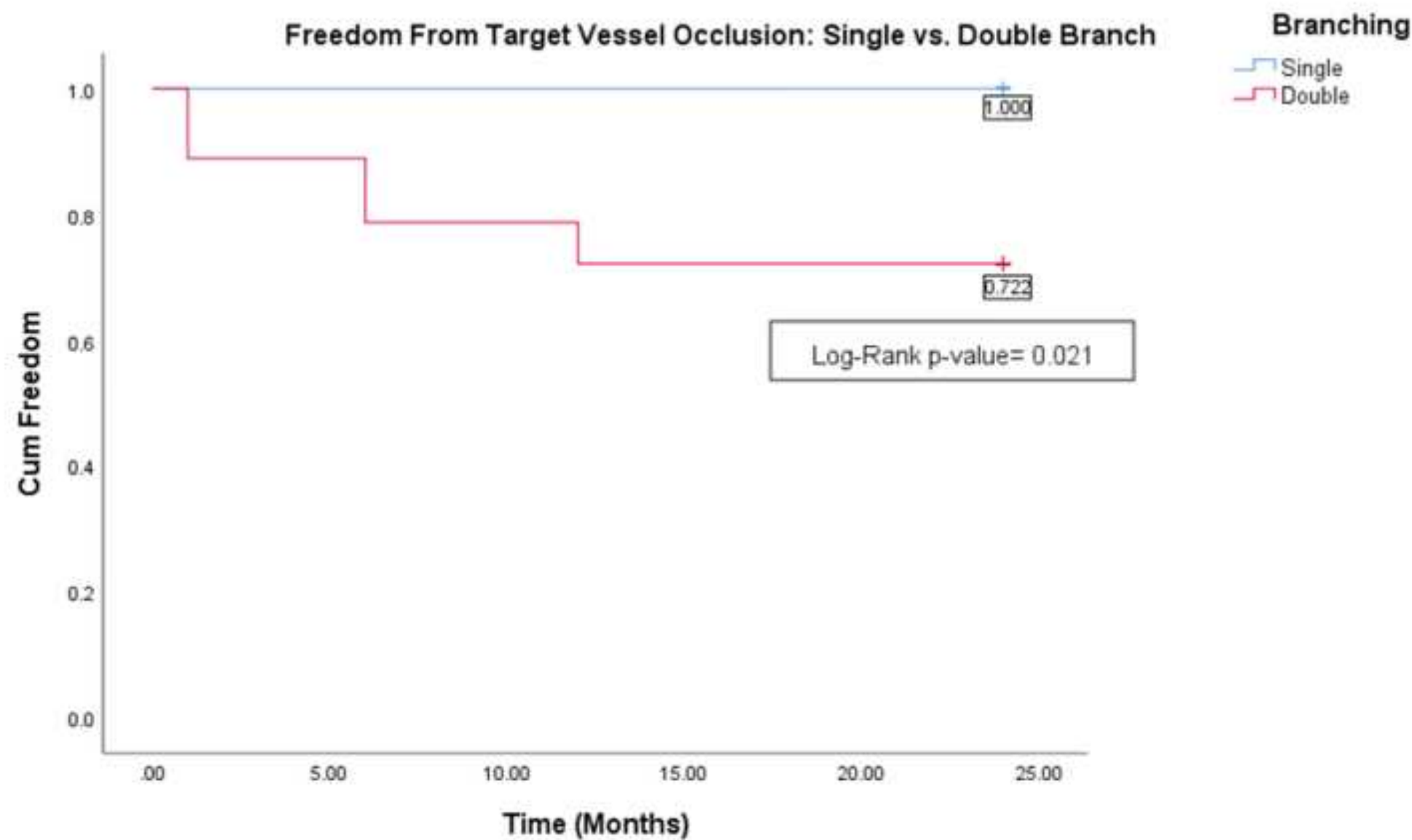


Fig. 8. Kaplan-Meier Freedom from Target Vessel Occlusion: Single versus Double Branch.

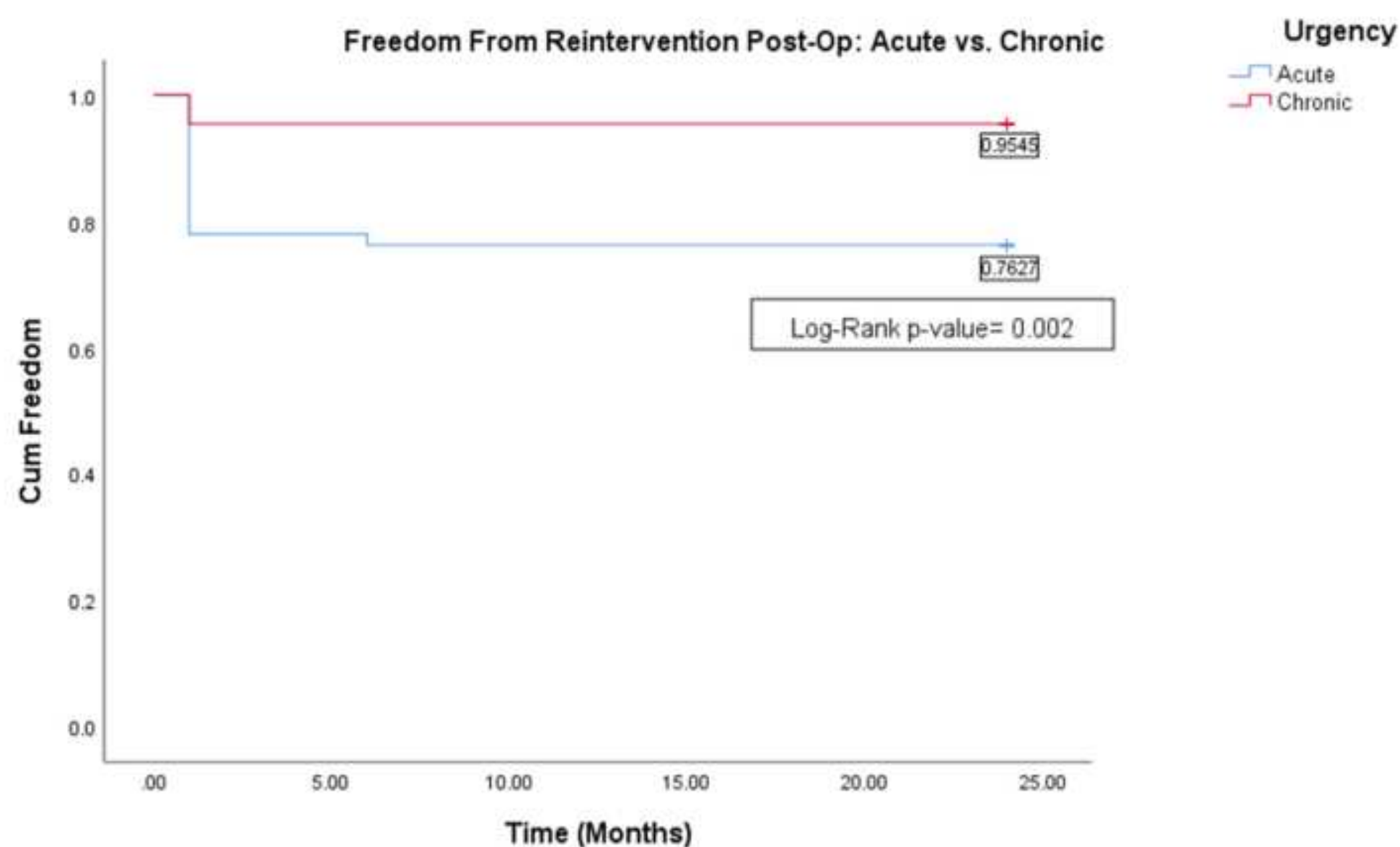


Fig. 9. Kaplan-Meier Freedom from Reintervention: Acute versus Chronic.

either group. Nevertheless this RELAY Branched experience provides a solid foundation for future studies investigating EAR.

CONCLUSION

Despite the well-established nature of OSR in the literature, EAR is proving to be a superior approach to treating thoracic aortic pathologies involving the arch while also expanding its applicability and indications. Our series has shown

through its results that EAR using RELAY Branched is a highly efficacious strategy, yielding very favorable results including excellent survival, lower incidence of neurological complications, high and maintained TVP, and a comparable need for reintervention. Nevertheless, it seems that clinical outcomes with the single-branch RELAY are more optimal than with the double-branch device. Importantly, beyond its results this study provides a solid foundation for future studies investigating EAR.

REFERENCES

1. Jubouri M, Al-Tawil M, Yip HCA, et al. Mid- and long-term outcomes of thoracic endovascular aortic repair in acute and subacute uncomplicated type B aortic dissection. *J Card Surg* 2022;37:1328–39.
2. Tan SZ, Jubouri M, Bashir M. Endovascular aortic arch repair: a comparison of outcomes and current trends. *Asian Cardiovasc Thorac Ann* 2022;. <https://doi.org/10.1177/02184923221140756>.
3. Hagan PG, Nienaber CA, Isselbacher EM, et al. The international registry of acute aortic dissection (IRAD): new insights into an old disease. *JAMA* 2000;283:897–903.
4. Leontyev S, Misfeld M, Daviewala P, et al. Early-and medium-term results after aortic arch replacement with frozen elephant trunk techniques—a single center study. *Ann Cardiothorac Surg* 2013;2:606–11.
5. Nordon IM, Hinchliffe RJ, Morgan R, et al. Progress in endovascular management of type A dissection. *Eur J Vasc Endovasc Surg* 2012;44:406–10.
6. Singh S, Surkhi AO, Tan SZ, et al. RELAY™ branched—international results of vessel patency and reintervention. *Front Cardiovasc Med* 2022;9:962884.
7. Riambau V, Zipfel B, Coppi G, et al. Final operative and midterm results of the European experience in the RELAY Endovascular Registry for Thoracic Disease (RESTORE) study. *J Vasc Surg* 2011;53:565–73.
8. Zipfel B, Zaefferer P, Riambau V, et al. Worldwide results from the RESTORE II on elective endografting of thoracic aneurysms and dissections. *J Vasc Surg* 2016;63:1466–75.
9. Tan SZ, Surkhi AO, Singh S, et al. Favorable neurological outcomes in thoracic endovascular aortic repair with RELAY™ branched—an international perspective. *J Card Surg* 2022;37:3556–63.
10. Sato H, Fukada J, Tamiya Y, et al. Long-term clinical outcomes of thoracic endovascular aortic repair for arch aneurysms with the Najuta thoracic stent-graft system. *Ann Vasc Dis* 2020;13:384–9.
11. O’Callaghan A, Mastracci TM, Greenberg RK, et al. Outcomes for supra-aortic branch vessel stenting in the treatment of thoracic aortic disease. *J Vasc Surg* 2014;60:914–20.
12. Clough RE, Modarai B, Topple JA. Predictors of stroke and paraplegia in thoracic aortic endovascular intervention. *Eur J Vasc Endovasc Surg* 2010;41:303–10.
13. Matsumura JS, Lee WA, Mitchell RS. The Society for Vascular Surgery Practice Guidelines: management of the left subclavian artery with thoracic endovascular aortic repair. *J Vasc Surg* 2009;50:1155–8.
14. Spear R, Haulon S, Ohki T, et al. Editor’s choice - subsequent results for arch aneurysm repair with inner branched endografts. *Eur J Vasc Endovasc Surg* 2016;51:380–5.
15. Iwakoshi S, Ichihashi S, Itoh H, et al. Clinical outcomes of thoracic endovascular aneurysm repair using commercially available fenestrated stent graft (Najuta endograft). *J Vasc Surg* 2015;62:1473–8.
16. Jubouri M, Bashir M, Tan SZCP, et al. What is the optimal timing for thoracic endovascular aortic repair in uncomplicated type B aortic dissection? *J Card Surg* 2022;37:993–1001.
17. Tan SZCP, Surkhi AO, Jubouri M, et al. Does endovascular duration impact clinical outcomes in aortic arch repair? The RELAY™ branched international stance. *Front Cardiovasc Med* 2022;9:969858.
18. Bashir M, Jubouri M, Patel R, et al. Cost analysis of thoracic endovascular aortic repair in type B aortic dissection: how much does quality cost? *Ann Vasc Surg* 2022.