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Original Article

Single-Centre Registry Analysis of Patients Who Underwent Percutaneous Coronary Intervention on Their Coronary Bypass Grafts

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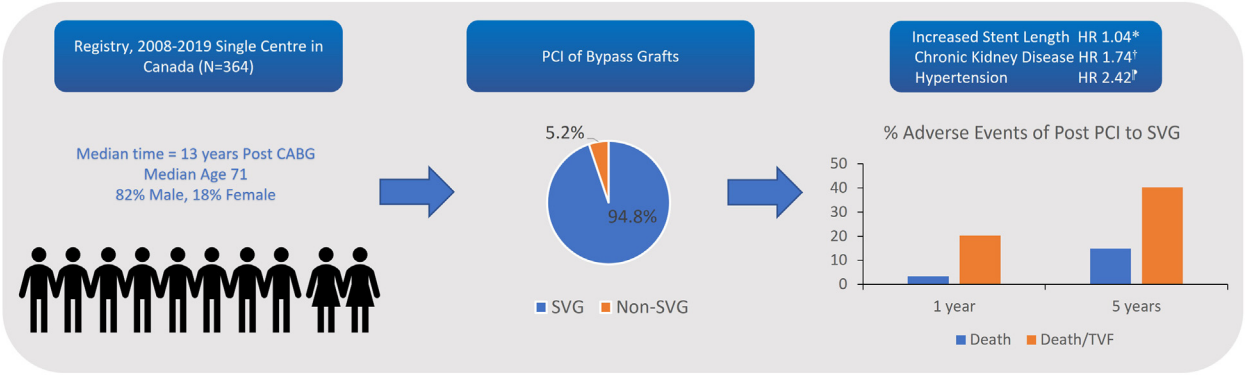

Having chronic kidney disease (HR 1.74 (95% CI 1.16 - 2.61), p=0.007)† was independently associated with mortality whereas hypertension (HR 2.42 (95% CI 1.32 – 4.42), P=0.004)‡ and increased stent length (HR 1.01 (95% CI 1.00 – 1.02), P=0.007) were independently associated with TVF or mortality in multivariable analyses.*

ABSTRACT

Background: The study assessed the outcomes of patients undergoing percutaneous coronary intervention (PCI) to bypass grafts, focusing on all-cause mortality and target vessel failure (TVF) rates.

Methods: A single-centre registry analysis included 364 patients who underwent PCI on coronary bypass grafts between 2008 and 2019. The study analyzed all-cause mortality and TVF, which encompassed target lesion revascularization, target vessel revascularization, and medically treated occluded target graft post-PCI.

Results: The median age of the patients was 71 years (interquartile range: [IQR] 65-78), with 82.1% being male. Most patients (94.8%) received PCI on saphenous vein grafts, and the median graft age was 13.0 years (IQR: 8.4-17.6). Drug-eluting stents were used more frequently (54.4%) than bare-metal stents (45.6%), with a median

RÉSUMÉ

Contexte : L'étude visait à évaluer l'issue des patients ayant subi une intervention coronarienne percutanée (ICP) sur un greffon coronarien, en mettant l'accent sur le taux de mortalité toutes causes confondues et le taux d'échecs de revascularisation du vaisseau cible (EVC).

Méthodologie : Une analyse du registre d'un seul établissement a porté sur 364 patients ayant subi une ICP sur un greffon coronarien de 2008 à 2019. L'étude a analysé la mortalité toutes causes confondues et les EVC, qui comprenaient la revascularisation de la lésion cible, la revascularisation du vaisseau cible et le traitement médical de l'occlusion du greffon coronarien cible après l'ICP.

Résultats : L'âge médian des patients était de 71 ans (intervalle interquartile [IIQ] de 65 à 78) et 82,1 % d'entre eux étaient de sexe masculin. La plupart des patients (94,8 %) avaient subi une ICP sur un

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stent diameter of 3.5 mm (IQR: 3-4) and length of 19 mm (IQR: 18-28). Outcome differences were not significant for PCI sites (aorto-ostial, graft body, anastomosis), use of drug-eluting stents, or use of protection devices. The 1-year mortality rate was 3.3%, whereas the combined rate of TVF or death was 20.3%. After 5 years, the mortality rate increased to 14.9%, and the combined TVF or death rate rose to 40.3%. Multivariable analyses revealed that chronic kidney disease was independently associated with mortality (hazard ratio [HR] 1.74, 95% confidence interval [CI] 1.16-2.61, $P = 0.007$), whereas hypertension (HR 2.42, 95% CI 1.32-4.42, $P = 0.004$) and increased stent length (HR 1.01, 95% CI 1.00-1.02, $P = 0.007$) were independently associated with the TVF-or-mortality outcome.

Conclusions: Patients undergoing PCI to bypass grafts experience considerable adverse outcomes over a 5-year period, highlighting the need for further strategies in managing this high-risk population.

greffon de veine saphène; l'âge médian des greffons était de 13,0 ans (IIQ de 8,4 à 17,6). Les endoprothèses médicamentées avaient été utilisées plus fréquemment (54,4 %) que les endoprothèses non médicamentées (45,6 %), le diamètre médian de l'endoprothèse étant de 3,5 mm (IIQ de 3 à 4) et sa longueur, de 19 mm (IIQ de 18 à 28). Les différences pour ce qui est de l'issue clinique n'étaient pas significatives à l'égard des sites d'ICP (aorto-ostial, corps du greffon, anastomose), de l'utilisation d'une endoprothèse médicamentée, ou encore de l'utilisation de dispositifs de protection. Le taux de mortalité à 1 an était de 3,3 %, alors que le taux combiné d'EVC ou de décès était de 20,3 %. Après 5 ans, le taux de mortalité avait augmenté à 14,9 %, alors que le taux combiné d'EVC ou de décès s'élevait à 40,3 %. Les analyses multivariables ont révélé que la néphropathie chronique était indépendamment associée au décès (rapport des risques instantanés [RRI] de 1,74, intervalle de confiance [IC] à 95 % de 1,16 à 2,61, $p = 0,007$), alors que l'hypertension (RRI de 2,42, IC à 95 % de 1,32 à 4,42, $p = 0,004$) et une longueur accrue de l'endoprothèse (RRI de 1,01, IC à 95 % de 1,00 à 1,02, $p = 0,007$) étaient indépendamment associées à une issue d'EVC ou de décès.

Conclusions : Les patients qui ont subi une ICP sur un greffon coronarien présentent des complications considérables sur une période de 5 ans, ce qui souligne le besoin de mettre en place davantage de stratégies de prise en charge pour cette population à risque élevé.

Coronary artery disease continues to be one of the leading causes of morbidity and mortality, despite the advances made in treatment in the past several decades.[1,2] Previous studies have shown that survival is improved more by coronary artery bypass grafting (CABG) than by optimal medical therapy in patients with left main or multivessel coronary artery disease.[3-5] However, despite revascularization with CABG, the disease process continues, and many are at risk for adverse outcomes partly because of graft failure; studies a decade ago reported venous graft failure rates of up to 40% in 10 years.[6-10] Evidence has been found in support of treating the native artery,[7,11,12] but percutaneous coronary intervention (PCI) on native vessels tends to involve chronic total occlusions or severely calcific diffusely diseased vessels, which elevates intraprocedural risk.[13] Alternatively, treating graft stenosis is challenging, and the best strategy is still being determined. In addition to comorbidities that predispose patients to adverse outcomes post-CABG, bypass grafts in themselves present a unique challenge for those needing PCI. Procedural factors, such as PCI sites, the use of drug-eluting stents vs bare-metal stents, and the use of filter wires, are among those thatcan affect patient outcomes. Whether these factors affect long-term outcomes following PCI of grafts is unknown in the contemporary era. Hence, we aimed to describe 1-year and 5-year clinical outcomes in these patients and identify predictors of worse outcomes.

Methods

This retrospective analysis included patients who had PCI performed on their bypass grafts at the Queen Elizabeth II Health Science Centre, Halifax, Nova Scotia, Canada from 2008 to 2019. Data in the study were retrieved from the Cardiovascular Health Information System database, which included all patients treated in the cardiac catheterization laboratory at the QEII Health Sciences Centre. This database includes patient demographics, procedural complications, devices used, and procedural outcomes. Each case was reviewed angiographically, and clinical outcome data were collected from our registry. The institutional research ethics board approved this study.

Target lesion revascularization was defined as any repeat percutaneous or bypass surgery performed on the target lesion. The target lesion was defined as the treated segment from 5 mm proximal to the stent to 5 mm distal to the stent. Target vessel revascularization (TVR) was defined as any repeat percutaneous intervention or surgical bypass of any segment of the target graft and the native coronary vessel distal to the graft anastomosis. Target vessel failure (TVF) was defined as the composite of target lesion revascularization, TVR, and medically treated occluded target graft post-procedure. Procedural success was defined as the achievement of no residual stenosis in the treated segment associated with thrombolysis in myocardial infarction (TIMI)-3 flow (or at least similar flow to the baseline flow if the baseline flow was TIMI-1 or TIMI-2), in the absence of dissection of more than D1, assessed according to the National Heart, Lung, and Blood Institute classification, without major clinical complications (such as death,

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See page 554 for disclosure information.

Table 1. Baseline characteristics of patients who underwent percutaneous coronary intervention on their bypass grafts

Patient characteristic	Value
Age, y	71 (65−78)
Male	299 (82.1)
Body mass index, kg/m^2	27.9 (24.7−31.9)
Diabetes	174 (47.8)
Hypertension	319 (87.6)
Dyslipidemia	264 (72)
Smoking	81 (22.3)
Chronic kidney disease	95 (26.1)
Time since CABG, y	13.0 (8.4−17.6)
Indication for the procedure	
STEMI	42 (11.5)
NSTEMI	117 (32.1)
Unstable angina	140 (38.5)
Stable angina	52 (14.3)
Other	13 (3.6)

Values are n (%) or median (interquartile range). Chronic kidney disease was defined as an estimated glomerular filtration rate of < 60 mL/min per 1.73 m^2.

CABG, coronary artery bypass grafting; NSTEMI, non-STEMI; STEMI, ST-elevation myocardial infarction.

Table 2. Procedural characteristics of patients who underwent PCI on their bypass grafts

Baseline characteristic	Value
Graft type	
SVG	345 (94.8)
LIMA	9 (2.5)
RIMA	5(1.4)
Radial	4 (1.1)
Other	1 (0.3)
Number of grafts	3 (2−3)
$\geq$ 1 occluded graft	142 (39)
Graft target vessel	
LAD	25 (6.9)
LCX	157 (43.1)
RCA	126 (34.6)
Diagonal	45 (12.4)
Graft flow	
TIMI 0	6 (1.6)
TIMI 1−2	48 (13.2)
TIMI 3	310 (85.2)
Lesion stenosis	
Occlusion	26 (7.1)
Moderate	10 (2.7)
Severe	328 (90.1)
Stent length, mm	19 (18−28)
Stent diameter, mm	3.5 (3−4)
Stent type	
DES	198 (54.4)
BMS	166 (45.6)
Protection device	79 (21.7)
Access	
Femoral	263 (72.3)
Radial	99 (27.2)
Brachial	2 (0.5)
OCT/IVUS use	3 (0.8)
Presence of thrombus	37 (10.2)
Graft site	
Ostial	83 (22.8)
Shaft	237 (65.1)
Anastomosis	44 (12.1)
Post PCI flow	
TIMI 3	355 (97.5)
TIMI 1−2	9 (2.4)
Procedural success	358 (98.4)

Values are n (%) or median (interquartile range). Lesion severity was defined as moderate for 50%−69% angiographic stenosis, and as severe for $\geq$ 70% angiographic stenosis.

BMS, bare-metal stent; DES, drug-eluting stent; IVUS, intravascular ultrasound; LAD, left anterior descending; LCX, left circumflex; LIMA, left internal mammary artery; OCT, optical coherence tomography; PCI, percutaneous coronary intervention; RCA, right coronary artery; RIMA, right internal mammary artery; SVG, saphenous vein graft; TIMI, thrombolysis in myocardial infarction.

myocardial infarction [MI], or emergency CABG) during hospitalization. Data were presented as median (interquartile range [IQR]) for continuous nonparametric data, and as count (percentage) for categorical data. The outcomes of mortality and combined mortality with TVF were characterized using Kaplan-Meier plots. One-year and 5-year survival rates were calculated. A multivariable Cox proportional hazards regression model was fit for time to mortality and time to combined mortality with TVF. The models were summarized using hazard ratios (HRs), with 95% confidence intervals (CIs), and the corresponding *P* values. The proportional hazards assumption was assessed using the Kolmogorov-type supremum test. A *P* value of < 0.05 indicated that the proportional hazards assumption did not hold. For these variables, a time interaction was included in the model. A 2-sided *P* value of < 0.05 was the threshold for statistical significance, unless otherwise specified. Multivariable analyses were performed using SAS statistical software version 9.4 (SAS Institute Inc., Cary, NC). The subgroup analyses by PCI sites, stent types, or usage of protection devices were characterized using Kaplan-Meier plots using SPSS Statistics version 27 (IBM, Armonk, NY). A 2-sided *P* value of < 0.05 was the threshold for statistical significance.

Results

A total of 364 patients were included in the study, and their baseline characteristics were retrieved (Table 1). The median age was 71 years (IQR 65-78), with 82.1% male patients, 47.8% with diabetes, and 26.1% with chronic kidney disease. Of those, 43.6% presented with acute myocardial infarction (non-ST-elevation MI [NSTEMI] or STEMI). PCI to saphenous vein grafts was done in 94.8%, whereas the rest of the cohort had PCI to arterial grafts (Table 2). The median time from CABG to graft PCI was 13.0 years (IQR 8.4-17.6). Drug-eluting stents were used in 54.4%, and bare-metal stents in 45.6%. A protection device was used in 21.7%. Ostial, mid-body, and distal anastomosis-site PCIs were done at the rates of 22.8%, 65.1%, and 12.1%, respectively. The acute procedural success rate was 98.4%. The median follow-up duration was 8.1 years (IQR 4.1-10.9). All-cause death occurred in 3.3%, and combined TVF or death occurred in 20.3% at 1 year. All-cause death occurred in 14.9%, and combined TVF or death occurred in 40.3% at 5 years (Fig. 1). No significant outcome differences occurred in locations of the PCI sites, use of drug-eluting stents, or use of protection devices (Fig. 2). Having chronic kidney disease (HR 1.74 [95% CI 1.16-2.61], $P = 0.007$) was independently associated with mortality, whereas hypertension (HR 2.42 [95% CI 1.32-4.42], $P = 0.004$) and increased stent length (HR 1.01

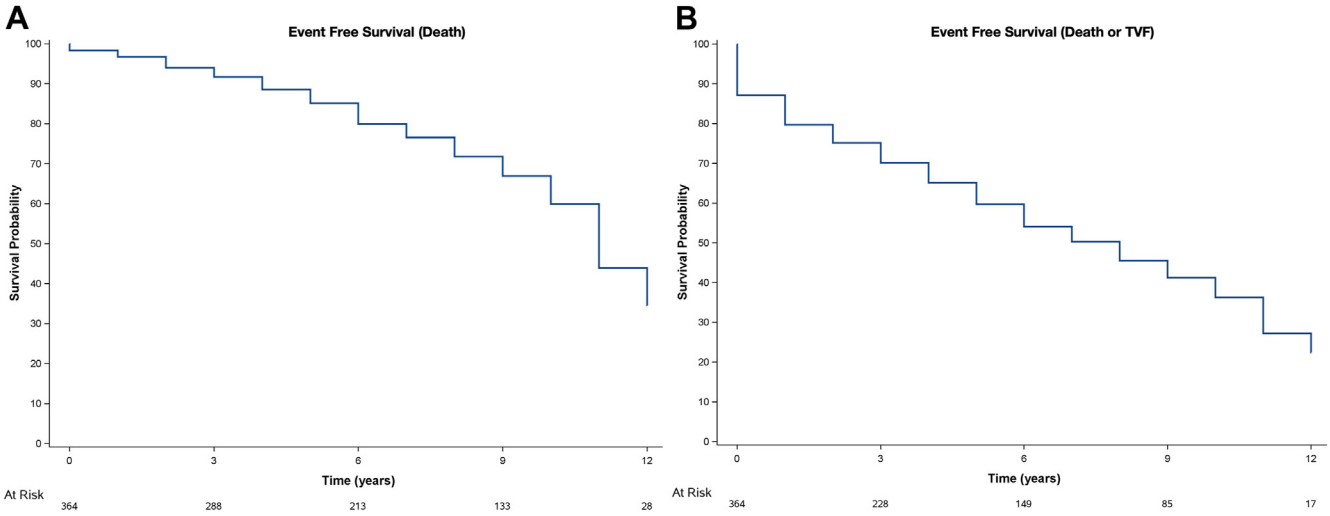

Figure 1. Kaplan-Meier plot of patients who received graft percutaneous coronary intervention. (**A**) Event-free survival (death); (**B**) event-free survival (death or target vessel failure [TVF]). BMS, bare-metal stent; DES, drug-eluting stent.

[95% CI 1.00-1.02], $P = 0.007$) were independently associated with TVF in multivariable analyses (Table 3).

Discussion

This study presents comprehensive 5-year outcome data of patients who underwent vein graft PCI, derived from a significant single-centre registry, enriching the current understanding of long-term outcomes in these patients. Although several recent registry studies and randomized trials have focused on shorter-term follow-up periods, ranging from 30 days to 2 years[11,13-16]), our findings fill a notable gap in the literature by offering insights based on contemporary data up to 2019. The uniqueness of this research is further underscored by the relative paucity of long-term data, with only one other study reporting 5-year outcomes, albeit from a cohort treated between 2008 and March 2013.[17] Consistent with earlier studies, our findings suggest that no definitive advantage comes with use of drug-eluting stents or protection devices. An interesting finding, and one previously unstudied, is that the specific sites of PCI in the vein graft did not seem to influence patient outcomes. Notably, our results identify chronic kidney disease as a potent predictor of increased mortality. Additionally, we observed that hypertension and stent lengths were both associated with the outcome of TVF or mortality, offering crucial clinical implications for patient management and future research directions.

Prior reports have demonstrated significantly elevated short- and medium-term outcomes of those receiving PCI for their grafts. Our study corroborates a recent report examining the outcomes of 405 graft PCI patients presenting with acute coronary syndrome (66%) or stable angina (44%), which showed rates of 1- and 2-year mortality (4.5% and 8.9%), TVF (20.4% and 33%), and ischemia-driven revascularization (13% and 21.3%) that were significantly higher than the rates for those receiving native-vessel PCI post-CABG.[11] Our study provides additional information, with a mortality rate of 14.9% at 5 years. Our population included patients with MI up to 43.6%, and we suspect that the 5-year mortality rate would be higher if we had included more patients with acute MI. Accordingly, the mortality rates post-graft PCI are higher in patients with acute coronary syndrome. For example, one report shows a 1-year mortality rate of 29.8% in 192 NSTEMI patients,[18] and another from the British registry examining approximately 9500 patients revealed a 7.1% 1-year mortality rate.[16]

Our study found that the use of drug-eluting stents did not lead to differences in outcomes. The use of drug-eluting and bare-metal stents in vein grafts has been reported previously. Some of these studies showed more benefits to using first- and second-generation drug-eluting stents,[17,19,20] whereas others showed no significant difference.[15,21,22] The randomized study comparing a second-generation drug-eluting stent and a bare-metal stent in 597 patients from 2012 to 2015 showed no significant difference in cardiac death, target-vessel MI, or TVR after 1 year (17% vs 19%, $P = 0.70$).[15] Similarly, a randomized study of 610 patients from 2007 and 2010 reported equivocal clinical outcomes at 5 years for drug-eluting stents and bare-metal stents, respectively, in terms of cardiovascular death (18.2% vs 20.1%, $P = 0.67$), MI (8.2% vs 9.9%, $P = 0.37$), and TVR (39.5% vs 32.9%, $P = 0.57$).[22] Our study is in line with these findings, with equivocal results for the drug-eluting stents compared to the bare-metal stents in patients who had PCI from 2008 to 2019. The reason for such findings is thought to be the intrinsic atherosclerotic disease progression in vein grafts that are exposed to high arterial pressures, which makes them prone to more diffuse, concentric, and early neointimal growth, in comparison to native coronaries. which may predispose them to early degeneration and failure despite implantation of drug-eluting stents. [23,24]

Regarding protection device use, thus far, a single randomized controlled trial of 801 patients showed benefits in reducing 30-day outcomes, driven by a lower incidence of MI (8.6% vs 14.7%, $P = 0.008$), which was reported decades ago.[25] A subsequent randomized trial has shown no significant benefit, although the trial had early termination due to slow

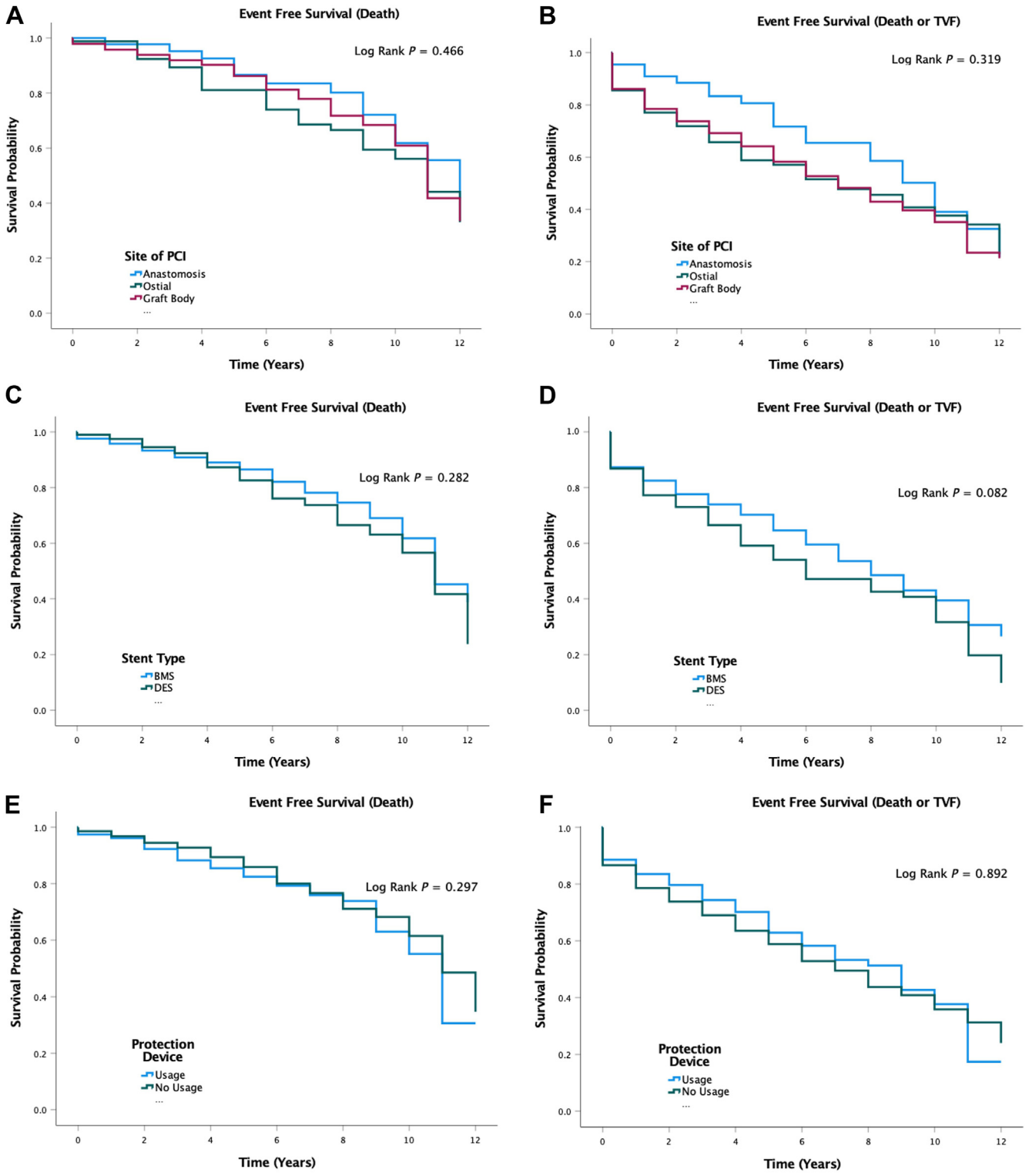

Figure 2. Kaplan-Meier plot of patients who received graft percutaneous coronary intervention (PCI). Subgroups had no statistically significant differences in either overall survival or event-free survival (death or target vessel failure [TVF]) analyzed by (**A, B**) PCI locations, (**C, D**) stent types, and (**E, F**) usage of protection devices.

enrollment.[26] Several subsequent large registry studies showed conflicting results.[14,27-29] A protection device was used in our study in up to 21.7% of cases, and it did not show any statistically significant benefit. similar to findings in the large registry report.[28] The anticipated benefit of a protection device may be difficult to observe, as several factors may play a role in mitigating its effect. In the contemporary era, vein graft stenting with no-reflows or periprocedural MIs, which these

Table 3. Multivariable Cox proportional hazards regression model

Characteristic	Death	*P*	Death or TVF	*P*
Age (1-y increase)	1.022 (1, 1.045)	0.053	0.992 (0.975, 1.008)	0.311
Female gender	0.869 (0.52, 1.45)	0.591	0.977 (0.664, 1.437)	0.904
Hypertension*	1.092 (0.513, 2.3261)	0.819	2.415 (1.321, 4.415)	0.004
Smoking	1.021 (0.622, 1.675)	0.936	1.156 (0.809, 1.653)	0.427
Diabetes	1.443 (0.969, 2.149)	0.071	1.346 (0.993, 1.825)	0.055
Chronic kidney disease	1.741 (1.162, 2.608)	0.007	1.259 (0.908, 1.746)	0.167
Saphenous vein graft	0.695 (0.346, 1.399)	0.308	1.227 (0.645, 2.335)	0.533
Graft age (1-mo increase)	1.001 (0.999, 1.004)	0.293	1.001 (0.999, 1.002)	0.645
Bare-metal stent	1.21 (0.784, 1.867)	0.389	0.795 (0.559, 1.13)	0.201
Stent diameter (1-mm increase)	1.278 (0.894, 1.826)	0.178	0.826 (0.617, 1.106)	0.200
Stent length (1-mm increase)	1.011 (0.999, 1.023)	0.067	1.013 (1.004, 1.022)	0.007
Protection device	1.062 (0.68, 1.658)	0.790	1.147 (0.801, 1.643)	0.453

Values are hazard ratio (95% confidence interval), unless otherwise indicated. Chronic kidney disease was defined as an estimated glomerular filtration rate of < 60 mL/min per 1.73 m^2.

TVF, target vessel failure.

*The proportional hazards assumption did not hold for hypertension; therefore, it was included in the model with a time interaction with hazard ratio at 5 years specifically.

devices are meant to prevent, also could be facilitated by aggressive platelet inhibition, vasodilators, and improved PCI techniques, such as direct stenting. Also, use of a protection device in certain lesions and small-diameter grafts can be associated with dissection, perforation, and device entrapment, which can be associated with longer procedural times.[28] Overall, we believe protection devices have utility, but their routine use in vein graft PCI should be undertaken with caution.

Stenting of aorto-ostial diseases in native coronaries is associated with higher rates of geographical misses and adverse outcomes compared to non-ostial lesions.[30-32] No such data have been reported for vein grafts, and in that regard, our study found no significant difference in outcomes based on the location of the PCI in the vein grafts. No studies have reported such findings previously. In our analysis, a trend was present toward increased TVF or death with PCI sites at the aorto-ostial and graft body positions, compared to the anastomotic sites, but this did not reach statistical significance. This finding again may be driven by several factors, such as the progressive nature of the disease in the vein graft, and comorbidities of patients in this population.

Despite the development of newer-generation stents and pharmacotherapy, our 5-year mortality rates still do not appear to be drastically improved from a few decades ago; at that time, a report of 177 patients with graft PCI with acute coronary syndrome from 1991 to 1995 showed a 4-year mortality rate of 21% and an adverse event rate of 71% (death, MI, repeat CABG, and repeat catheter-based intervention).[33] Such an adverse trend appeared consistent, despite developments in 2000-2010,[34] as well as the past decade, with studies reporting a 1-year TVF rate of 19%[15], and 5-year rates of mortality, MI, or TVR of up to 56.1% in 173 patients.[17]

This phenomenon likely is driven by the fact that patients undergoing PCI post-CABG tend to be older and to carry more comorbidities, predisposing them to higher event rates that cannot be mitigated further by the contemporary armamentaria in cardiovascular care. Our data (Supplemental Fig. S1) also corroborated these findings, as we did not find any significant outcome differences between the 2 periods of 2008-2013 and 2014-2019. Despite improved operator skills, techniques, and the use of contemporary equipment in the latter half of the analysis, these factors appear not to affect outcomes of patients who had PCI on their vein grafts. The predisposition of the patient population to adverse outcomes. which is generally true of most patients who have had CABG compared to those who have not, as well as aggressive disease progression in the vein grafts,[23,24] may account for these findings.

Regression analysis evaluated possible factors that are independently associated with TVF and mortality. The results showed that having a baseline estimated glomerular filtration rate of less than 60 mL/min per 1.73 m^2 was a factor significantly associated with mortality. Multiple studies have demonstrated previously that adverse outcomes increase, including all cause-death, in patients with renal insufficiency undergoing revascularization via PCI or CABG.[35-38] Our study provides affirmation that renal insufficiency is a strong predictor of mortality in patients undergoing graft PCIs after their initial revascularization. Having hypertension and longer stents proved to be factors associated with combined TVF or death. Hypertension and longer stent length are known risk factors for in-stent restenosis, which likely contributed significantly to TVF.[39,40] Our finding emphasizes the importance of the reduction of clinical and procedural risk factors for the TVF-or-death outcome post-graft PCI.

Strengths and Limitations of the Study

One of the key strengths of this analysis is the inclusion of a relatively large number of patients with 5-year outcomes, utilizing the most up-to-date data available up to 2019 from a single centre in North America. Our results indicate that the utilization of drug-eluting stents or protective devices was not associated with reduced 5-year adverse event rates. Additionally, we observed that the location of the PCI sites within the vein graft did not appear to impact the outcomes, which is a new finding. Our study did, however, identify that chronic kidney disease was independently linked to an increased mortality rate, whereas hypertension and stent lengths were associated with a higher risk of an outcome of TVF or mortality.

The study limitations include the inherent issues of retrospective studies, with missing data, and the selection bias from being from a single centre. Complete follow-up data are

potentially missing, given the study's nature. Further studies using a case-control approach or collection of prospective data are needed. In addition, studies are needed to optimize graft intervention outcomes vs alternative strategies, such as complex native coronary artery intervention, including chronic total occlusions. This field is evolving currently. One study reported no significant 1-year mortality rate (3.10% vs 3.46%, $P = 0.36$) or TVR rate (5.6% vs 7.27%, $P = 0.08$) difference between graft PCI vs native chronic total occlusion PCI, respectively, in a large British registry.[13] On the other hand, a recent meta-analysis found that native-vessel PCI was associated with a lower rate of major adverse cardiovascular events and all-cause death, compared with bypass graft PCI, at a median follow-up of 2 years.[12] Evidence of how these rates would fare over a time period of 5 years or more is currently limited.

Conclusion

Our study indicates that individuals with stable and acute coronary syndromes who have undergone graft PCI in the past decade experienced a significant rate of mortality or TVF at 1 and 5 years. These findings suggest that these patients are vulnerable to adverse consequences, such as death, and returning for TVF treatment. Further studies are needed to optimize graft intervention outcomes vs alternative strategies, such as native coronary intervention, including for chronic total occlusions.

Ethics Statement

The institutional research ethics board approved this study.

Patient Consent

The authors confirm that patient consent is not applicable to this article and that the Nova Scotia Health Authority Research Ethics Board (NSHA ROMEO File #: 1025312) approved the study and did not require consent.

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Disclosures

The authors have no conflicts of interest to disclose.

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Supplementary Material

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