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Joint Patient-Level Analysis of Saphenous Vein Graft Occlusion and Bleeding in the TOP-CABG Randomised Trial

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Abstract

Text Abstract

Background
Trials after coronary artery bypass grafting commonly report saphenous vein graft occlusion and bleeding separately, obscuring their overlap within participants.

Aims
To describe the joint patient-level distribution of one-year saphenous vein graft occlusion and clinically relevant bleeding in a randomised trial comparing 12 and 3 months of dual antiplatelet therapy after coronary artery bypass grafting.

Methods
This secondary analysis aggregated graft observations for each participant with evaluable one-year imaging. Four mutually exclusive categories described neither outcome, graft occlusion without bleeding, bleeding without graft occlusion, and both. Treatment groups were compared using an unadjusted multinomial model. Occlusion burden and analyses addressing missing imaging were examined.

Results
Among 2,070 participants with evaluable imaging, 71.8% had neither outcome, 17.3% had graft occlusion without bleeding, 8.5% had bleeding without graft occlusion, and 2.3% had both. The distributions were 69.8%, 16.8%, 10.2%, and 3.2% with 12-month dual antiplatelet therapy and 73.9%, 17.8%, 6.8%, and 1.4% with 3-month therapy (global P = 0.00164). Relative to neither outcome, relative risk ratios were 1.00 (95% confidence interval 0.79–1.26), 1.57 (1.14–2.16), and 2.34 (1.26–4.34), respectively. Among 407 participants with any graft occlusion, 287 had one and 120 had multiple occluded grafts. Analyses addressing missing imaging gave similar directional findings.

Conclusions
Joint patient-level reporting revealed within-participant overlap between graft occlusion and bleeding and added information on graft-occlusion multiplicity to conventional endpoint summaries.

Trial registration number: NCT05380063

Introduction

Coronary artery bypass grafting remains central to the treatment of complex coronary artery disease, and saphenous vein grafts (SVGs) are widely used when more than one conduit is required. Vein graft occlusion is common enough to matter for the durability of revascularisation and has been associated with later clinical events, repeat procedures, and survival in long-term angiographic studies [1–3]. Antiplatelet treatment after surgery is intended to reduce thrombotic graft occlusion, but greater platelet inhibition can increase bleeding. Randomised trials and meta-analyses have therefore examined both

graft patency and bleeding across several postoperative antiplatelet strategies [4–7]. These outcomes answer different clinical questions. Imaging describes whether one or more grafts remain open, whereas bleeding is experienced by the patient. A treatment duration that changes either outcome must ultimately be interpreted for the person receiving it. Early occlusion may reflect technical, anatomical, and thrombotic factors, whereas bleeding ranges from events requiring medical attention to life-threatening complications. Their clinical consequences are therefore not interchangeable, even when both are relevant to the duration of postoperative antiplatelet therapy.

Separate reports of graft occlusion and bleeding leave their within-participant overlap unresolved. A participant with an occluded graft and no clinically relevant bleeding differs from one who has bleeding despite no observed graft occlusion, and both differ from a participant with both outcomes. Cross-classifying the two outcomes at the patient level preserves component identity while showing their overlap within the same participant. This produces four mutually exclusive nominal categories while retaining the original component outcomes. The usual binary indicator of any graft occlusion treats one occluded graft and several occluded grafts as equivalent, even though one participant may contribute several graft observations while treatment assignment and bleeding are recorded once per participant. Reporting the number of occluded grafts additionally distinguishes single from multiple SVG occlusions.

TOP-CABG compared 12 months with 3 months of dual antiplatelet therapy after coronary artery bypass grafting and reported its primary graft and bleeding outcomes separately [8]. The public trial data permit graft-level imaging observations to be reconstructed for each participant and linked to clinically relevant bleeding recorded during follow-up. This setting allows a direct comparison of the four patient-level categories while preserving the randomised treatment groups and the published endpoint definitions. We therefore examined the publicly available TOP-CABG data to describe the joint patient-level distribution of one-year SVG occlusion and clinically relevant bleeding, quantify SVG occlusion multiplicity, and assess the robustness of these findings to missing imaging.

Methods

Study design and data source

This was a post hoc secondary analysis of the multicentre, double-blind TOP-CABG randomised trial [8, 9]. The trial compared two durations of dual antiplatelet therapy after coronary artery bypass grafting. We used the publicly available, de-identified participant, graft, imaging, and bleeding data deposited in Dryad [10]. The patient was the independent unit for every analysis reported here. No new outcomes were collected.

Trial population and treatment strategies

The randomised population comprised 2,290 participants: 1,138 assigned to 12-month dual antiplatelet therapy and 1,152 assigned to the 3-month strategy. The parent trial describes eligibility, operative care,

treatment allocation, masking, follow-up, and the original efficacy and safety estimands [8, 9]. The primary population for the present joint analysis included participants with evaluable one-year saphenous vein graft imaging. Baseline characteristics were summarised by randomised treatment without significance testing.

Patient-level reconstruction of SVG occlusion

Each graft record was linked to its participant identifier. A participant was classified as having any SVG occlusion when at least one evaluable saphenous vein graft was occluded on one-year imaging; otherwise the participant was classified as having no observed SVG occlusion. Participants without evaluable one-year imaging were excluded from the complete-case analysis. The original graft-level definitions were retained after aggregation to the patient level.

Joint SVG occlusion and bleeding categories

Clinically relevant bleeding was defined as Bleeding Academic Research Consortium type 2, 3, or 5 bleeding during trial follow-up [11]. Among participants with evaluable imaging, SVG occlusion status was cross-classified with bleeding into four mutually exclusive categories: neither SVG occlusion nor clinically relevant bleeding; SVG occlusion without clinically relevant bleeding; clinically relevant bleeding without SVG occlusion; and both SVG occlusion and clinically relevant bleeding. The 'both' category reflects within-participant overlap across the observation periods rather than simultaneous event timing.

SVG occlusion burden

The number of occluded SVGs per participant was summarised as 0, 1, or at least 2. The ≥ 2 category was used as a descriptive multiplicity category. The patient-level fraction of evaluable SVGs that were occluded was summarised using the median and interquartile range. Because this variable was highly discrete and dominated by zero values, groups were compared using a two-sided Wilcoxon rank-sum test with a normal approximation and no continuity correction.

Statistical analysis

Joint categories were analysed as nominal outcomes. An unadjusted multinomial logistic model compared 12-month with 3-month therapy, using the category with neither outcome as the reference. We report the global likelihood-ratio test and relative risk ratios with 95% confidence intervals. Absolute treatment differences are percentage-point differences calculated as 12-month minus 3-month therapy with Wald confidence intervals. The burden categories were examined with an analogous multinomial model using zero occluded grafts as the reference. Inverse-probability weighting used the probability of imaging completion estimated from randomised treatment and available baseline variables; weight diagnostics and robust weighted-mean variance conditional on the estimated weights were reported

[12]. Common extreme assignments, a common-probability analysis, and a site-adjusted model were used to examine sensitivity to missing imaging and site. A proportional-odds model was evaluated only as a diagnostic because the four categories lacked a prespecified natural ordering or clinical utility weights; the proportional-odds assumption was not supported [13]. The global likelihood-ratio test provided the overall treatment comparison; state-specific estimates were used to describe the components of that distribution. No multiplicity adjustment was applied to these secondary component estimates.

Ethics

The parent TOP-CABG trial was approved by the Ethics Committee of Fuwai Hospital (approval number 2022 – 1774) and by the ethics committees of participating centres, as reported in the trial protocol and primary publication. The trial was conducted in accordance with applicable ethical principles. The present study was a secondary analysis of publicly available, de-identified trial data and involved no new participant contact or intervention.

Consent

Written informed consent was obtained from participants in the parent TOP-CABG trial as previously reported. The present secondary analysis used publicly available de-identified data and contains no identifiable individual-level material.

Data availability

The de-identified TOP-CABG data are publicly available from Dryad [10] (doi:10.5061/dryad.jsxksn0qs).

Code availability

The R code used for the analyses and preparation of manuscript figures and tables is available from the corresponding author on reasonable request.

Use of artificial intelligence tools

OpenAI ChatGPT and Codex were used to assist with code generation, language editing, manuscript organisation, format checks, and preparation of draft graphical and data displays. All analytical definitions, statistical outputs, effect estimates, interpretations, figure content, and final manuscript decisions were reviewed and approved by the authors, who take full responsibility for the submitted work.

Results

Study population and patient-level outcome structure

Of 2,290 randomised participants, 2,070 had evaluable one-year SVG imaging: 1,033 in the 12-month group and 1,037 in the 3-month group. Imaging was unavailable for 220 participants. Baseline characteristics were broadly similar between treatment groups, including age, sex, diabetes, left ventricular ejection fraction, renal function, and number of saphenous vein grafts; the complete tabulation is shown in Table 1 and Supplementary Table S1. Among imaging-evaluable participants, 1,487 (71.8%) had neither SVG occlusion nor clinically relevant bleeding, 359 (17.3%) had SVG occlusion without clinically relevant bleeding, 176 (8.5%) had clinically relevant bleeding without SVG occlusion, and 48 (2.3%) had both outcomes. Thus, 407 participants had any SVG occlusion and 224 had clinically relevant bleeding, while 583 had at least one of the two outcomes. The 583 comprised 359 with SVG occlusion alone, 176 with bleeding alone, and 48 with both (Fig. 1; Supplementary Table S2).

Table 1
Baseline characteristics

Characteristic	12-month therapy	3-month therapy	Standardised mean difference
Randomised participants, n	1,138	1,152	
Age, years	61.6 (8.5)	61.3 (8.3)	0.040
Male sex, n (%)	902 (79.3)	916 (79.5)	-0.006
Diabetes, n (%)	479 (42.1)	509 (44.2)	-0.042
Left ventricular ejection fraction, %	59.8 (8.1)	59.8 (8.0)	-0.003
Estimated glomerular filtration rate, mL/min/1.73 m^2	94.6 (14.9)	94.3 (15.4)	0.017
SYNTAX score, available n	1,055	1,067	
SYNTAX score	29.8 (11.6)	31.2 (11.7)	-0.113
Number of SVGs	2.46 (0.75)	2.51 (0.76)	-0.067

Values are mean (standard deviation) or n (%). Baseline P values were not calculated. SVG, saphenous vein graft.

[FIGURE 1 NEAR HERE]

Joint SVG occlusion and bleeding outcomes by randomised treatment

In the 12-month group, the four joint categories contained 721, 174, 105, and 33 participants, respectively; in the 3-month group, the corresponding counts were 766, 185, 71, and 15. The joint distribution differed between the randomised strategies (likelihood-ratio chi-square = 15.22, 3 degrees of freedom; P = 0.00164). Absolute differences were − 4.07 percentage points (95% confidence interval −

7.94 to -0.20) for neither outcome, -1.00 (-4.26 to 2.27) for SVG occlusion without clinically relevant bleeding, 3.32 (0.92 to 5.72) for clinically relevant bleeding without SVG occlusion, and 1.75 (0.45 to 3.04) for both outcomes (Table 2 and Fig. 2). Relative to neither outcome, the relative risk ratio for 12-month versus 3-month therapy was 1.00 (0.79–1.26) for SVG occlusion without bleeding, 1.57 (1.14–2.16) for bleeding without SVG occlusion, and 2.34 (1.26–4.34) for both outcomes (Supplementary Table S3). In the randomised population, clinically relevant bleeding occurred in 149 of 1,138 participants assigned to 12 months and 95 of 1,152 assigned to 3 months, consistent with the parent trial report [8].

Table 2
Joint patient-level SVG occlusion and bleeding outcomes

Category	12-month therapy n (%)	3-month therapy n (%)	Difference percentage points (95% CI)	RRR (95% CI)
J0: Neither SVG occlusion nor clinically relevant bleeding	721 (69.8)	766 (73.9)	-4.07 (-7.94 to -0.20)	Reference
J1: SVG occlusion without clinically relevant bleeding	174 (16.8)	185 (17.8)	-1.00 (-4.26 to 2.27)	1.00 (0.79–1.26)
J2: Clinically relevant bleeding without SVG occlusion	105 (10.2)	71 (6.8)	3.32 (0.92–5.72)	1.57 (1.14–2.16)
J3: Both SVG occlusion and clinically relevant bleeding	33 (3.2)	15 (1.4)	1.75 (0.45–3.04)	2.34 (1.26–4.34)

n = 2,070. Differences are 12-month minus 3-month therapy. Global likelihood-ratio P = 0.00164. Clinically relevant bleeding denotes Bleeding Academic Research Consortium type 2, 3, or 5. CI, confidence interval; RRR, relative risk ratio; SVG, saphenous vein graft.

[FIGURE 2 NEAR HERE]

Patient-level SVG occlusion burden

Across the imaging-evaluable cohort, 1,663 participants had no occluded SVG, 287 had one, and 120 had at least two. The corresponding proportions were 80.0%, 14.0%, and 6.0% in the 12-month group and 80.7%, 13.7%, and 5.6% in the 3-month group. Among the 407 participants with any SVG occlusion, 287 (70.5%) had one occluded graft and 120 (29.5%) had multiple occluded grafts. In the burden model, relative risk ratios were 1.03 (0.81–1.33) for one versus zero occluded grafts and 1.08 (0.75–1.57) for at least two versus zero, comparing 12-month with 3-month therapy (Fig. 3; Supplementary Table S4). The median patient-level occlusion fraction was 0 (interquartile range 0–0) in both groups; the Wilcoxon rank-sum comparison is reported in Supplementary Table S4.

[FIGURE 3 NEAR HERE]

Sensitivity to missing imaging

Inverse-probability weighting produced absolute differences close to the complete-case estimates: -4.04 percentage points (95% confidence interval − 7.90 to -0.18) for neither outcome, -0.93 (-4.18 to 2.33) for SVG occlusion without bleeding, 3.33 (0.97 to 5.69) for bleeding without SVG occlusion, and 1.63 (0.37 to 2.90) for both. The mean inverse completion weight was 1.108, the 1st to 99th percentile range was 1.022–1.809, the full range was 1.015–3.127, and the effective sample size was 2,029.5. Under common extreme assignments for missing imaging, the direction of each joint-category difference was unchanged whether all missing imaging was assigned no SVG occlusion or SVG occlusion. A common-probability analysis across q = 0 to 1 also showed no direction reversal. The site-adjusted model gave a global P = 0.00201 and relative risk ratios of 0.99, 1.56, and 2.33 for the three non-reference categories. These analyses are summarised in Fig. 4, with detailed results in Supplementary Tables S5-S8.

[FIGURE 4 NEAR HERE]

Discussion

Among 2,070 TOP-CABG participants with evaluable one-year imaging, almost three quarters had neither SVG occlusion nor clinically relevant bleeding, 17.3% had SVG occlusion without bleeding, 8.5% had bleeding without SVG occlusion, and 2.3% had both. The randomised groups differed in this four-category distribution. The 12-month strategy had more participants in the two bleeding-related categories, while the proportion with SVG occlusion without bleeding was similar between groups. Of the 407 participants with any SVG occlusion, 120 had at least two occluded grafts. Complete-case, weighted, extreme-assignment, common-probability, and site-adjusted analyses gave a consistent directional account of the group differences. The absolute difference for SVG occlusion without bleeding was − 1.00 percentage point and its confidence interval crossed zero, while differences for bleeding without occlusion and both outcomes were 3.32 and 1.75 percentage points. These findings add a within-participant view of graft occlusion and bleeding to the original treatment-effect estimates. The global comparison summarises the four-category distribution, while category-specific estimates show which components contribute to the difference.

A conventional 'either outcome' composite would identify 583 participants, but that total comprises 359 with SVG occlusion without bleeding, 176 with bleeding without SVG occlusion, and 48 with both. Cross-classification preserves this component information and displays within-participant overlap. Because no prespecified clinical utility weights or natural ordering were available, the four categories were analysed as nominal states rather than as a weighted or ordinal net-clinical-benefit measure.

The present analysis extends the reporting of the TOP-CABG trial by adding within-participant overlap and SVG occlusion multiplicity to the conventional graft and bleeding outcomes [8]. The parent study estimated treatment effects for graft-level efficacy and bleeding using methods suited to those endpoints. Earlier trials and pooled analyses similarly focused on graft patency while reporting bleeding

separately [4–7]. Graft-level analyses retain conduit-specific information and account for correlation among grafts within a participant, whereas the present reconstruction answers a complementary question: how were graft occlusion and bleeding distributed within the same participants? The observed difference between strategies was concentrated in categories containing bleeding, whereas SVG occlusion without bleeding was similar between groups. The crude bleeding counts in the randomised population were 149 of 1,138 with 12-month therapy and 95 of 1,152 with 3-month therapy, consistent with the parent trial report [8].

Cross-classification provides information that is not available from either marginal endpoint alone. Any SVG occlusion identified 407 participants, of whom 29.5% had multiple occluded grafts; bleeding identified 224 participants, including 48 who also had at least one occluded graft on one-year imaging. Prespecifying this type of cross-classification alongside conventional graft-level models would allow future trials to report component counts, within-participant overlap, and graft multiplicity without replacing the original endpoint analyses. Where clinical ordering or weighting is of interest, those values should be specified prospectively.

The analysis has limitations. The four-category outcome was not a prespecified endpoint of the parent trial. One-year imaging was unavailable for 220 of 2,290 participants; weighting and missing-outcome analyses supported the direction of the findings but remain dependent on observed covariates or explicit assumptions. Only 48 participants had both outcomes, leaving substantial uncertainty for that category. Finally, the analysis was restricted to the variables and follow-up structure available in the public TOP-CABG dataset; one-year imaging and bleeding recorded during follow-up describe within-participant overlap rather than simultaneous event timing. The analysis addresses population-level interpretation of trial outcomes and was not designed to estimate individual treatment effects.

Conclusions

Differences between the randomised treatment strategies were concentrated in bleeding-related outcome categories, whereas SVG occlusion without bleeding and the frequency of multiple SVG occlusions were similar between groups. By resolving within-participant overlap and SVG occlusion burden, this analysis adds patient-level context to the original TOP-CABG treatment-effect estimates.

Declarations

Conflict of Interest

Conflict of interest: none declared.

Author Contributions / CRediT

Donglin Xu: Conceptualization; Data curation; Formal analysis; Methodology; Software; Validation; Visualization; Writing – original draft; Writing – review and editing.

Zhen Yu: Data curation; Validation; Writing – review and editing.

Ang Li: Data curation; Validation; Writing – review and editing.

Zengkun Liu: Data curation; Validation; Writing – review and editing.

Qiduo Chen: Data curation; Validation; Writing – review and editing.

Jing Liu: Validation; Writing – review and editing.

Hourong Sun: Conceptualization; Funding acquisition; Project administration; Supervision; Writing – review and editing.

All authors reviewed and approved the final manuscript.

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Author Contribution

D.X.: Conceptualization, data curation, formal analysis, methodology, software, validation, visualization, writing—original draft, and writing—review and editing. Z.Y., A.L., Z.L., and Q.C.: Data curation, validation, and writing—review and editing. J.L.: Validation and writing—review and editing. H.S.: Conceptualization, funding acquisition, project administration, supervision, and writing—review and editing. All authors reviewed and approved the final manuscript.

Acknowledgement

We thank the TOP-CABG investigators for making the de-identified trial data publicly available through Dryad.

Data Availability

The de-identified TOP-CABG trial data analysed in this study are publicly available from Dryad: https://doi.org/10.5061/dryad.jsxksn0qs. No new participant-level data were collected.

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Figures

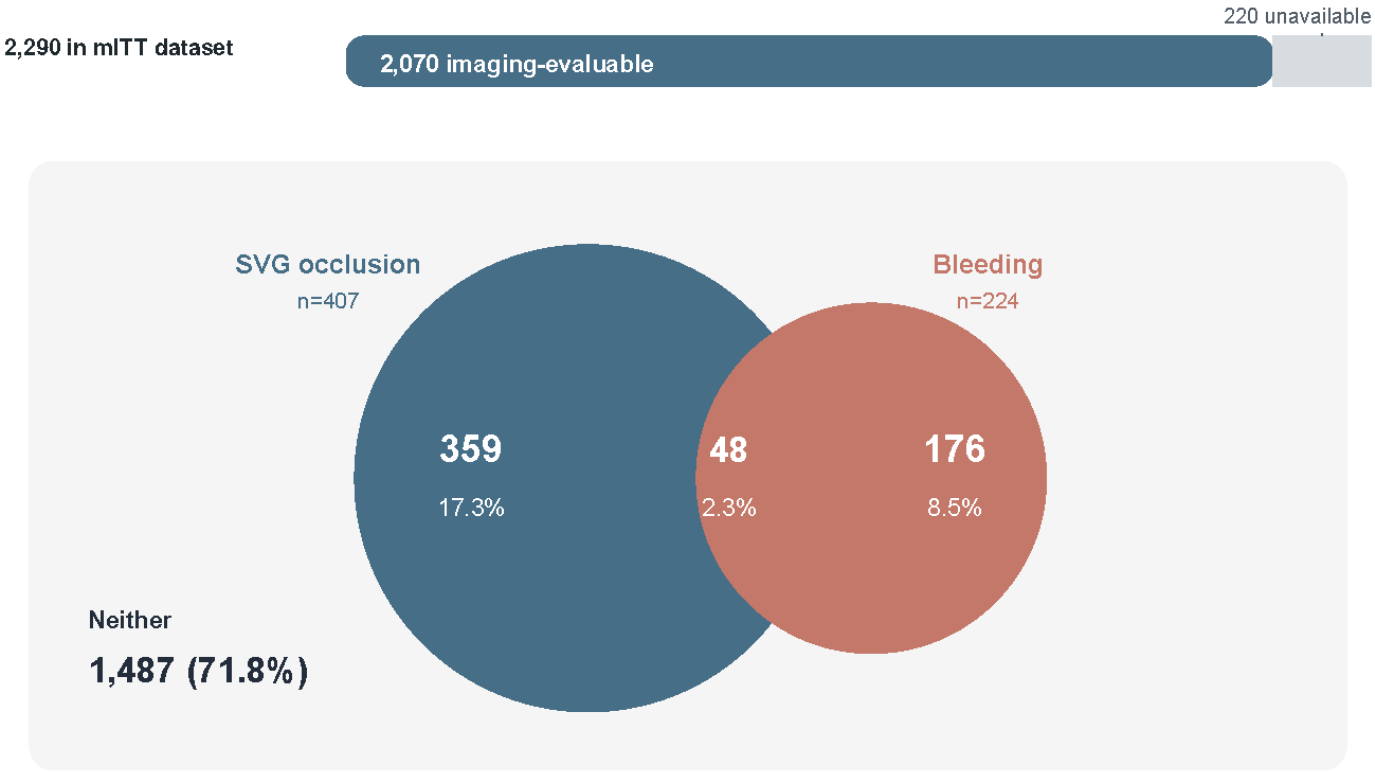


Figure 1

Overlap between SVG occlusion and clinically relevant bleeding. The denominator ribbon shows 2,290 randomised participants, including 2,070 with evaluable one-year imaging and 220 without evaluable imaging; 1,138 were assigned to 12-month and 1,152 to 3-month therapy. In the Euler diagram, SVG occlusion was assessed on one-year imaging and clinically relevant bleeding during follow-up. Among 2,070 imaging-evaluable participants, 359 had SVG occlusion only, 176 had bleeding only, 48 had both, and 1,487 had neither; 583 (28.2%) had at least one component. SVG, saphenous vein graft.

Alt text: A narrow denominator ribbon sits above an Euler diagram showing 359 participants with SVG occlusion only, 176 with bleeding only, 48 with both, and 1,487 with neither outcome.

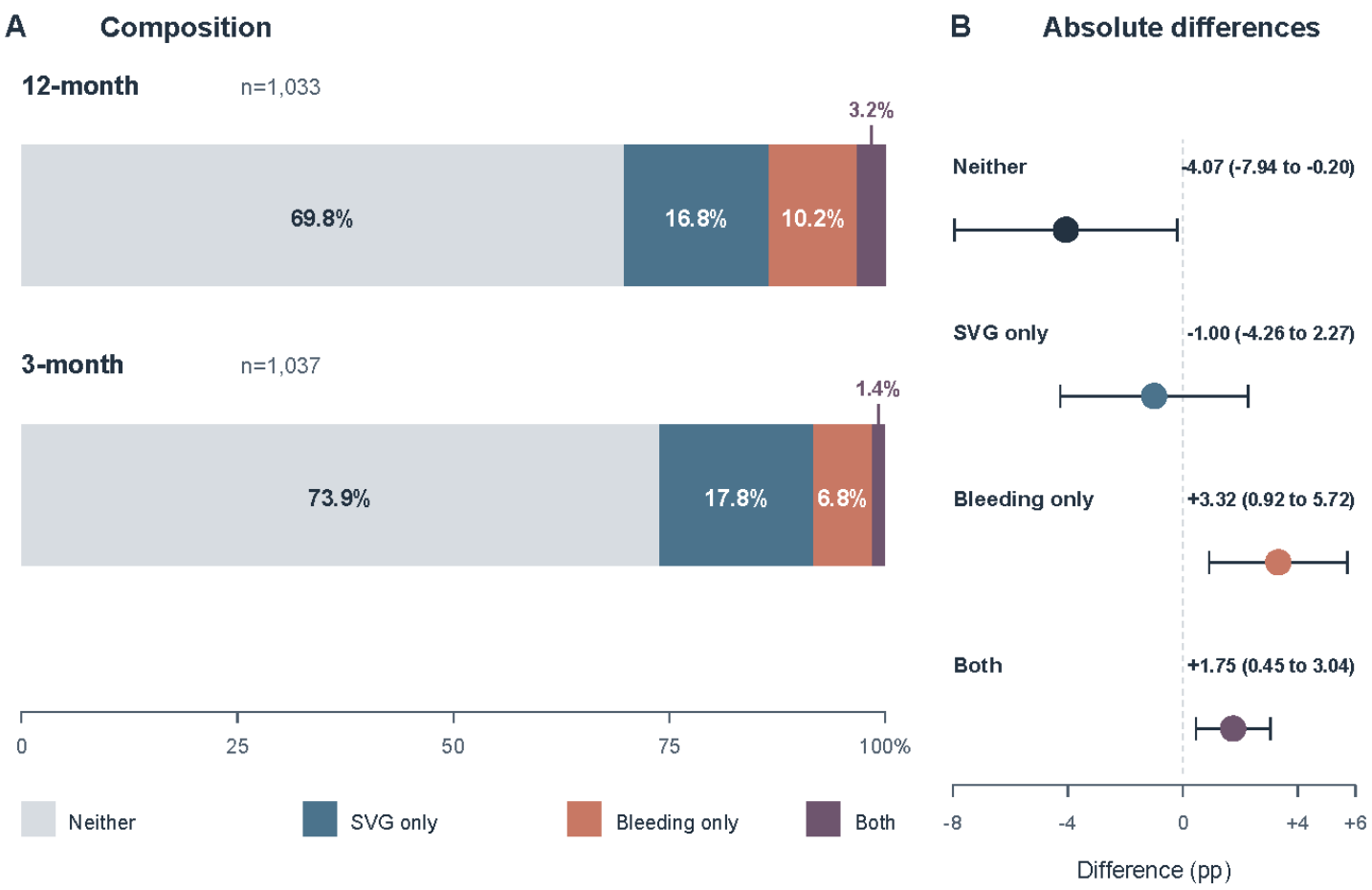


Figure 2

Outcomes by randomised DAPT strategy. (A) Percentage composition of four mutually exclusive states for 12-month therapy (n=1,033: 721 neither, 174 SVG occlusion without bleeding, 105 bleeding without SVG occlusion, and 33 both) and 3-month therapy (n=1,037: 766, 185, 71, and 15, respectively). (B) Absolute percentage-point differences with 95% confidence intervals, calculated as 12-month minus 3-month therapy. The global likelihood-ratio P value was 0.00164. CI, confidence interval; DAPT, dual antiplatelet therapy; SVG, saphenous vein graft.

Alt text: Two stacked bars compare the percentage composition of four outcome states, and a compact coefficient plot shows four absolute differences with confidence intervals.

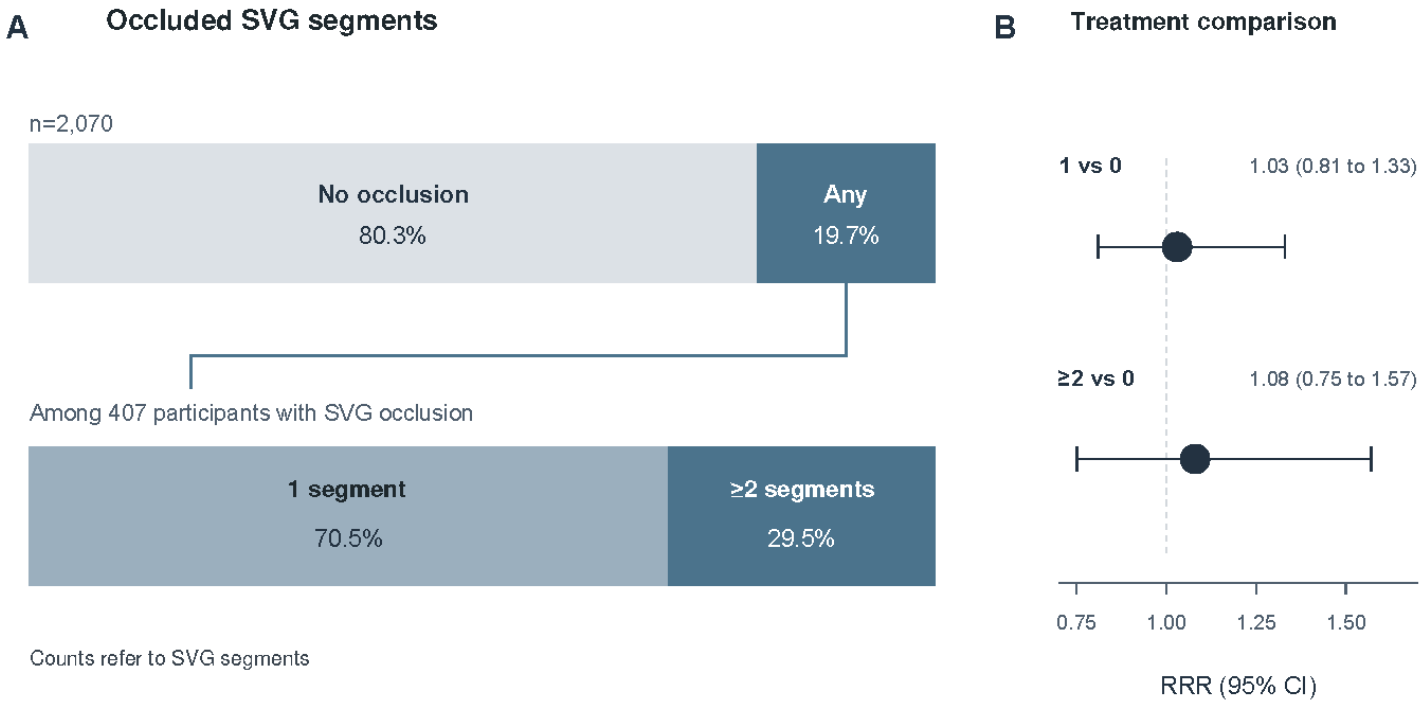


Figure 3

SVG occlusion burden. (A) Among 2,070 imaging-evaluable participants, 1,663 (80.3%) had no occluded SVG and 407 (19.7%) had any occlusion; among those 407 participants, 287 (70.5%) had one and 120 (29.5%) had at least two occluded SVGs. (B) Burden-model relative risk ratios with 95% confidence intervals, comparing 12-month with 3-month therapy and using zero occluded SVGs as the reference. CI, confidence interval; RRR, relative risk ratio; SVG, saphenous vein graft.

Alt text: Two horizontal percentage ribbons show no versus any SVG occlusion and, among participants with occlusion, one versus at least two occluded grafts; a compact forest plot shows two burden-model estimates.

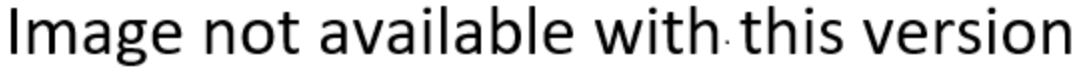


Figure 4

Sensitivity analyses. (A) Absolute percentage-point differences for complete-case, inverse-probability-weighted, two extreme missing-imaging assignments, and common-probability q=0.5 analyses; columns represent neither outcome, SVG occlusion without bleeding, bleeding without SVG occlusion, and both. Differences are 12-month minus 3-month therapy, and direction was preserved across q=0 to 1. q denotes the assumed common probability of SVG occlusion among participants with missing imaging. (B) Complete-case and inverse-probability-weighted estimates with 95% confidence intervals. (C) Unadjusted and site-adjusted relative risk ratios with 95% confidence intervals. Global P values were 0.00164 and 0.00201, respectively. CI, confidence interval; IPW, inverse-probability weighting; RRR, relative risk ratio; SVG, saphenous vein graft.

Alt text: A large heatmap shows stable directions across five sensitivity analyses; two compact right-side plots compare complete-case with weighted differences and unadjusted with site-adjusted relative risk ratios.

Supplementary Files

This is a list of supplementary files associated with this preprint. Click to download.

- ESM1.pdf