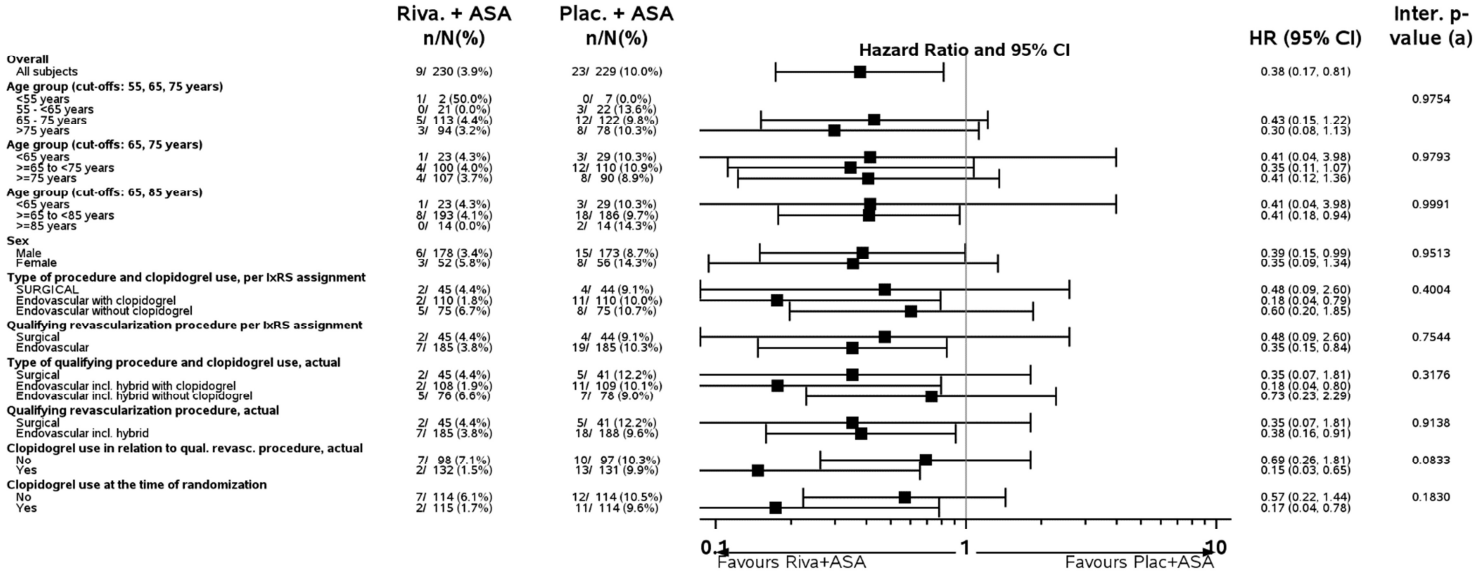
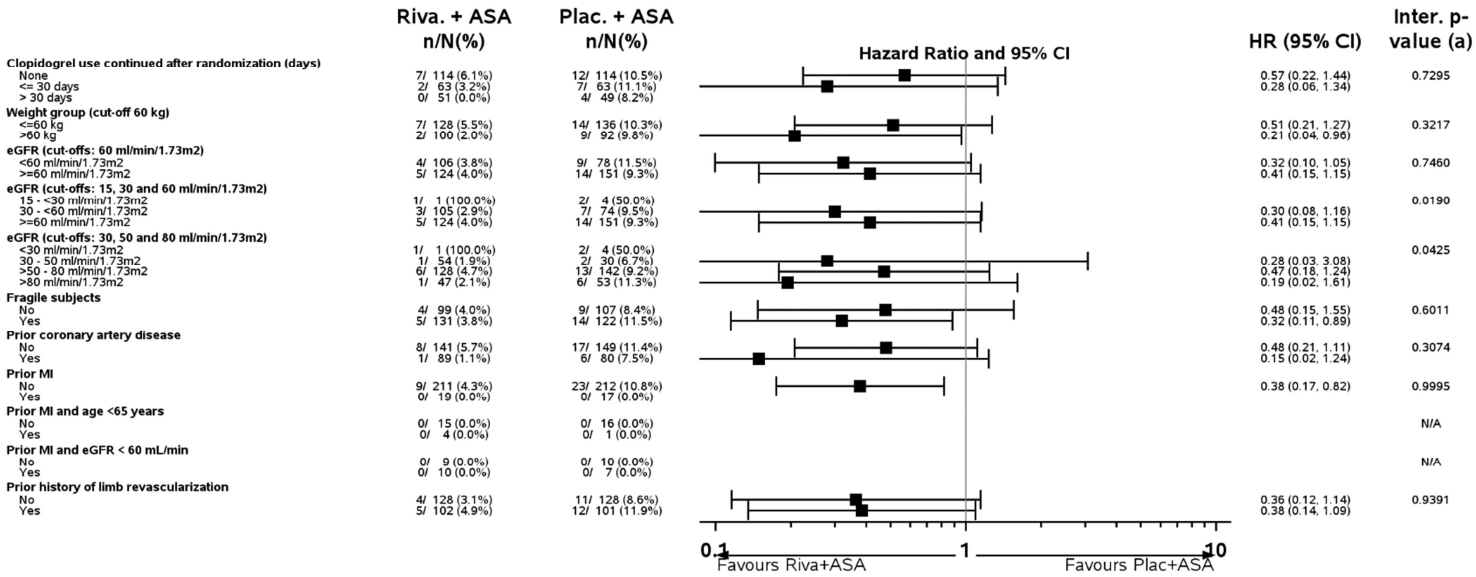
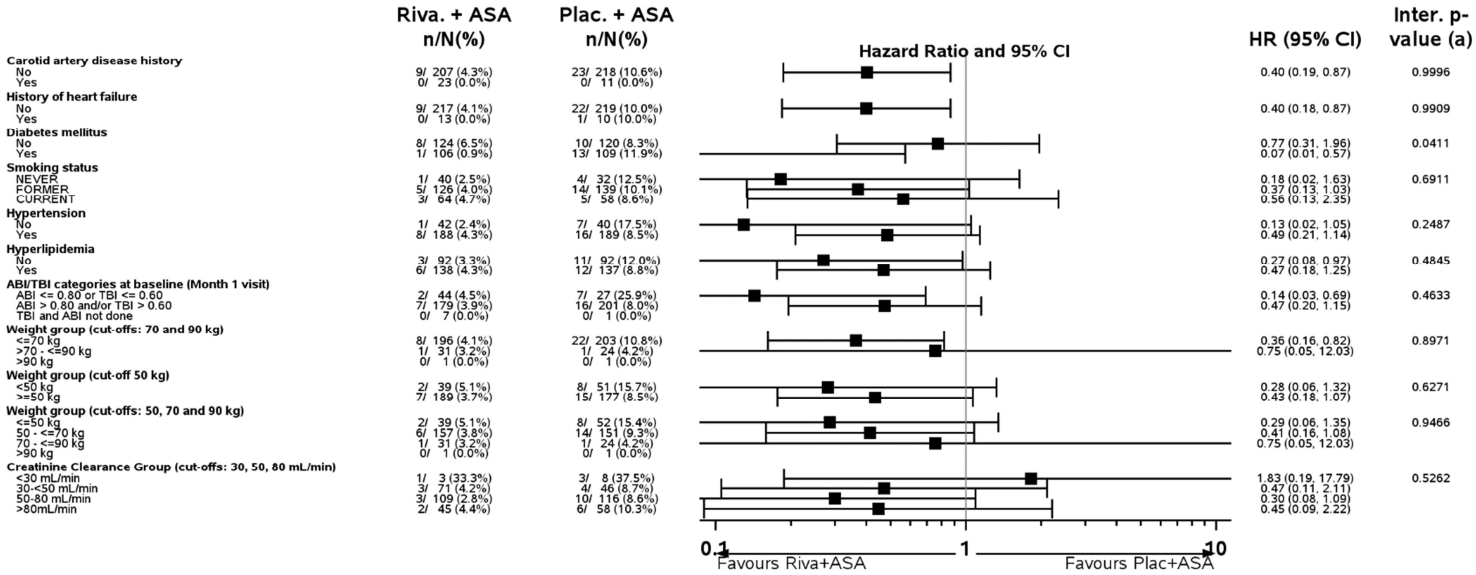
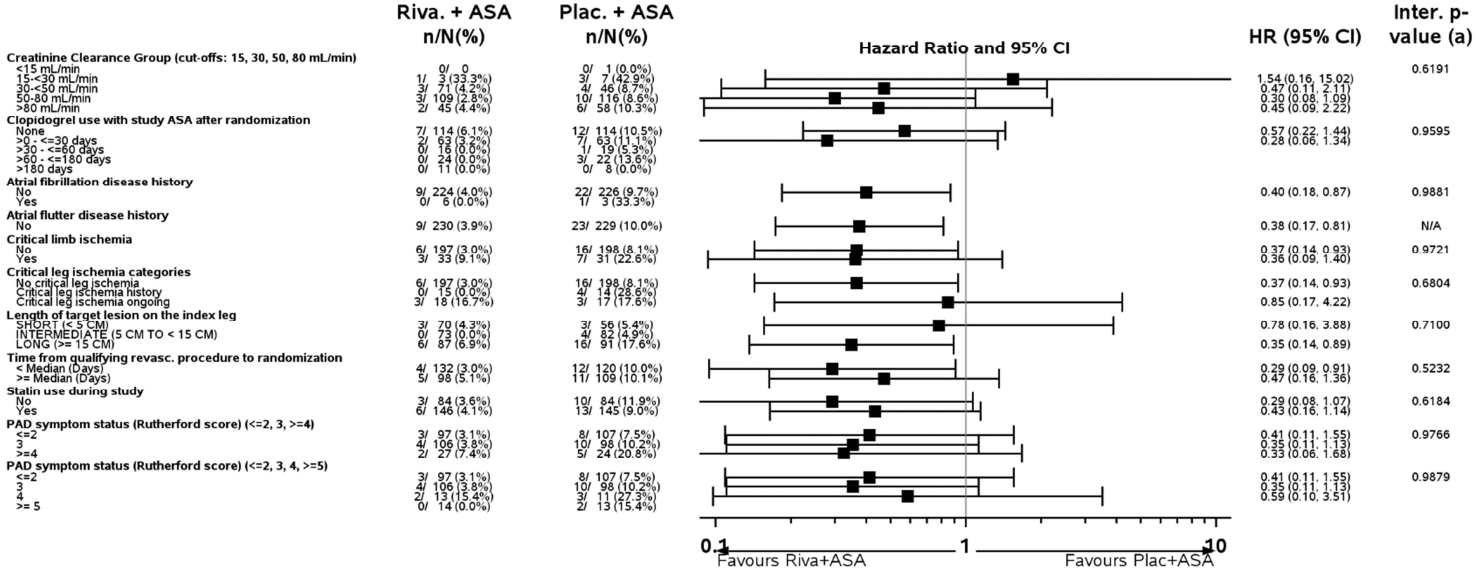
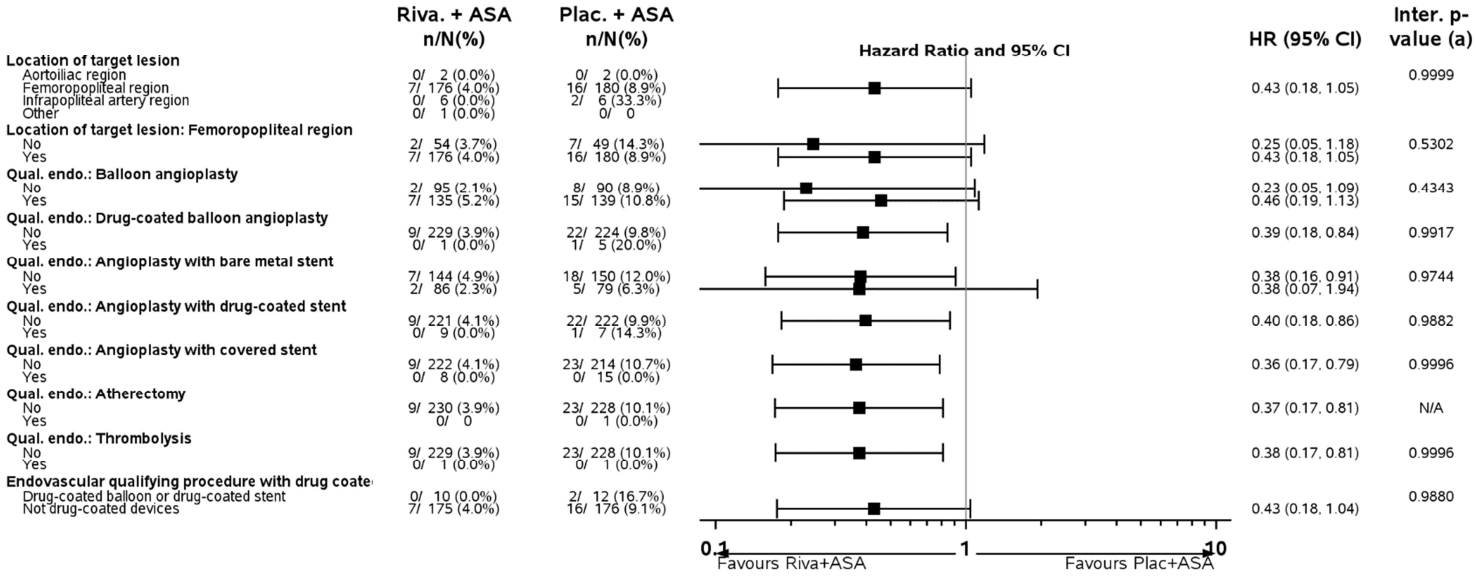
図 2.7.3.7-9 冠動脈又は末梢血管（いずれかの下肢）の血栓性イベントによる入院の Forest プロット（試験 17454、日本人集団、ITT、ECOD まで、ICAC 判定）




Riva. + ASA n/N(%)
Plac. + ASA n/N(%)
Hazard Ratio and 95% CI
HR (95% CI)
Inter. p-value (a)
Clopidogrel use continued after randomization (days)
None 7/ 114 (6.1%) 12/ 114 (10.5%) 0.57 (0.22, 1.44) 0.7295
<= 30 days 2/ 63 (3.2%) 7/ 63 (11.1%) 0.28 (0.06, 1.34)
> 30 days 0/ 51 (0.0%) 4/ 49 (8.2%)
Weight group (cut-off 60 kg)
<=60 kg 7/ 128 (5.5%) 14/ 136 (10.3%) 0.51 (0.21, 1.27) 0.3217
>60 kg 2/ 100 (2.0%) 9/ 92 (9.8%) 0.21 (0.04, 0.96)
eGFR (cut-offs: 60 ml/min/1.73m2)
<60 ml/min/1.73m2 4/ 106 (3.8%) 9/ 78 (11.5%) 0.32 (0.10, 1.05) 0.7460
>=60 ml/min/1.73m2 5/ 124 (4.0%) 14/ 151 (9.3%) 0.41 (0.15, 1.15)
eGFR (cut-offs: 15, 30 and 60 ml/min/1.73m2)
15 - <30 ml/min/1.73m2 1/ 1 (100.0%) 2/ 4 (50.0%) 0.0190
30 - <60 ml/min/1.73m2 3/ 105 (2.9%) 7/ 74 (9.5%) 0.30 (0.08, 1.16)
>=60 ml/min/1.73m2 5/ 124 (4.0%) 14/ 151 (9.3%) 0.41 (0.15, 1.15)
eGFR (cut-offs: 30, 50 and 80 ml/min/1.73m2)
<30 ml/min/1.73m2 1/ 1 (100.0%) 2/ 4 (50.0%) 0.0425
30 - 50 ml/min/1.73m2 1/ 54 (1.9%) 2/ 30 (6.7%) 0.28 (0.03, 3.08)
>50 - 80 ml/min/1.73m2 6/ 128 (4.7%) 13/ 142 (9.2%) 0.47 (0.18, 1.24)
>80 ml/min/1.73m2 1/ 47 (2.1%) 6/ 53 (11.3%) 0.19 (0.02, 1.61)
Fragile subjects
No 4/ 99 (4.0%) 9/ 107 (8.4%) 0.48 (0.15, 1.55) 0.6011
Yes 5/ 131 (3.8%) 14/ 122 (11.5%) 0.32 (0.11, 0.89)
Prior coronary artery disease
No 8/ 141 (5.7%) 17/ 149 (11.4%) 0.48 (0.21, 1.11) 0.3074
Yes 1/ 89 (1.1%) 6/ 80 (7.5%) 0.15 (0.02, 1.24)
Prior MI
No 9/ 211 (4.3%) 23/ 212 (10.8%) 0.38 (0.17, 0.82) 0.9995
Yes 0/ 19 (0.0%) 0/ 17 (0.0%)
Prior MI and age <65 years
No 0/ 15 (0.0%) 0/ 16 (0.0%) N/A
Yes 0/ 4 (0.0%) 0/ 1 (0.0%)
Prior MI and eGFR < 60 mL/min
No 0/ 9 (0.0%) 0/ 10 (0.0%) N/A
Yes 0/ 10 (0.0%) 0/ 7 (0.0%)
Prior history of limb revascularization
No 4/ 128 (3.1%) 11/ 128 (8.6%) 0.36 (0.12, 1.14) 0.9391
Yes 5/ 102 (4.9%) 12/ 101 (11.9%) 0.38 (0.14, 1.09)
0.1
1
10
Favours Riva+ASA
Favours Plac+ASA


Riva. + ASA n/N(%)
Plac. + ASA n/N(%)
Hazard Ratio and 95% CI
HR (95% CI)
Inter. p-value (a)
Carotid artery disease history
No 9/ 207 (4.3%) 23/ 218 (10.6%) 0.40 (0.19, 0.87) 0.9996
Yes 0/ 23 (0.0%) 0/ 11 (0.0%)
History of heart failure
No 9/ 217 (4.1%) 22/ 219 (10.0%) 0.40 (0.18, 0.87) 0.9909
Yes 0/ 13 (0.0%) 1/ 10 (10.0%)
Diabetes mellitus
No 8/ 124 (6.5%) 10/ 120 (8.3%) 0.77 (0.31, 1.96) 0.0411
Yes 1/ 106 (0.9%) 13/ 109 (11.9%) 0.07 (0.01, 0.57)
Smoking status
NEVER 1/ 40 (2.5%) 4/ 32 (12.5%) 0.18 (0.02, 1.63) 0.6911
FORMER 5/ 126 (4.0%) 14/ 139 (10.1%) 0.37 (0.13, 1.03)
CURRENT 3/ 64 (4.7%) 5/ 58 (8.6%) 0.56 (0.13, 2.35)
Hypertension
No 1/ 42 (2.4%) 7/ 40 (17.5%) 0.13 (0.02, 1.05) 0.2487
Yes 8/ 188 (4.3%) 16/ 189 (8.5%) 0.49 (0.21, 1.14)
Hyperlipidemia
No 3/ 92 (3.3%) 11/ 92 (12.0%) 0.27 (0.08, 0.97) 0.4845
Yes 6/ 138 (4.3%) 12/ 137 (8.8%) 0.47 (0.18, 1.25)
ABI/TBI categories at baseline (Month 1 visit)
ABI <= 0.80 or TBI <= 0.60 2/ 44 (4.5%) 7/ 27 (25.9%) 0.14 (0.03, 0.69) 0.4633
ABI > 0.80 and/or TBI > 0.60 7/ 179 (3.9%) 16/ 201 (8.0%) 0.47 (0.20, 1.15)
TBI and ABI not done 0/ 7 (0.0%) 0/ 1 (0.0%)
Weight group (cut-offs: 70 and 90 kg)
<=70 kg 8/ 196 (4.1%) 22/ 203 (10.8%) 0.36 (0.16, 0.82) 0.8971
>70 - <=90 kg 1/ 31 (3.2%) 1/ 24 (4.2%) 0.75 (0.05, 12.03)
>90 kg 0/ 1 (0.0%) 0/ 1 (0.0%)
Weight group (cut-off 50 kg)
<50 kg 2/ 39 (5.1%) 8/ 51 (15.7%) 0.28 (0.06, 1.32) 0.6271
>=50 kg 7/ 189 (3.7%) 15/ 177 (8.5%) 0.43 (0.18, 1.07)
Weight group (cut-offs: 50, 70 and 90 kg)
<=50 kg 2/ 39 (5.1%) 8/ 52 (15.4%) 0.29 (0.06, 1.35) 0.9466
50 - <=70 kg 6/ 157 (3.8%) 14/ 151 (9.3%) 0.41 (0.16, 1.08)
70 - <=90 kg 1/ 31 (3.2%) 1/ 24 (4.2%) 0.75 (0.05, 12.03)
>90 kg 0/ 1 (0.0%) 0/ 1 (0.0%)
Creatinine Clearance Group (cut-offs: 30, 50, 80 mL/min)
<30 mL/min 1/ 3 (33.3%) 3/ 8 (37.5%) 1.83 (0.19, 17.79) 0.5262
30-<50 mL/min 3/ 71 (4.2%) 4/ 46 (8.7%) 0.47 (0.11, 2.11)
50-80 mL/min 3/ 109 (2.8%) 10/ 116 (8.6%) 0.30 (0.08, 1.09)
>80mL/min 2/ 45 (4.4%) 6/ 58 (10.3%) 0.45 (0.09, 2.22)
0.1
1
10
Favours Riva+ASA
Favours Plac+ASA

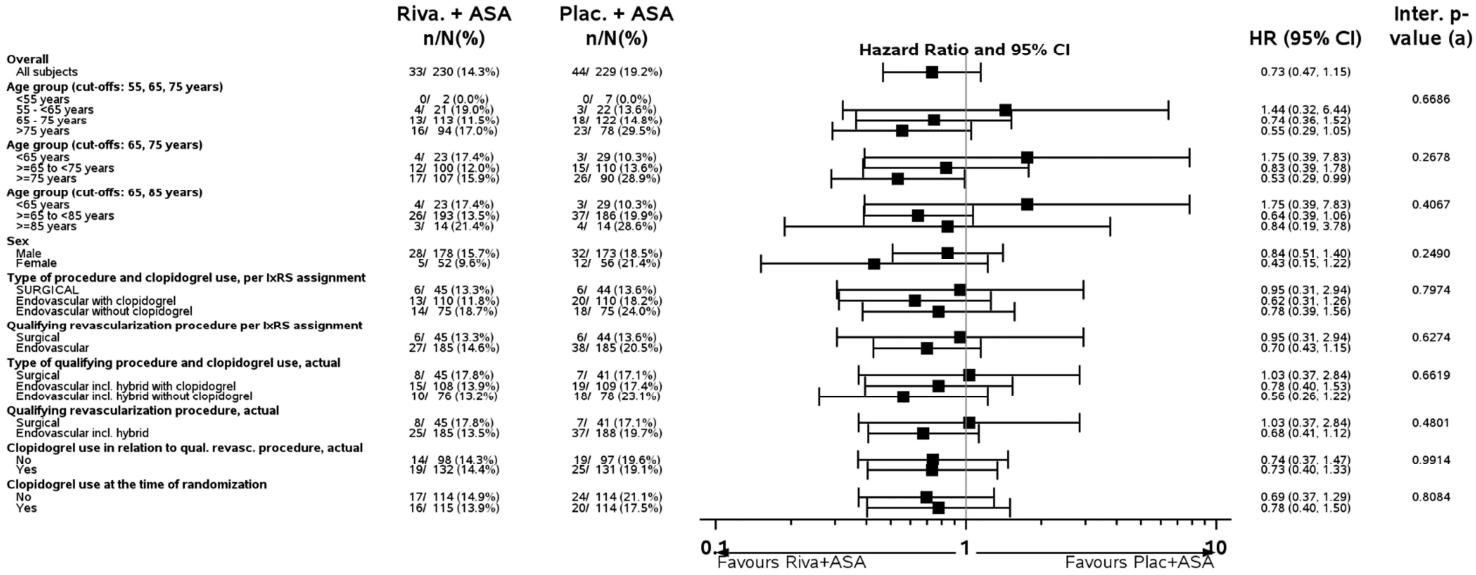

Riva. + ASA n/N(%)
Plac. + ASA n/N(%)
Hazard Ratio and 95% CI
HR (95% CI)
Inter. p-value (a)
Creatinine Clearance Group (cut-offs: 15, 30, 50, 80 mL/min)
<15 mL/min 0/ 0 0/ 1 (0.0%) 0.6191
15-<30 mL/min 1/ 3 (33.3%) 3/ 7 (42.9%) 1.54 (0.16, 15.02)
30-<50 mL/min 3/ 71 (4.2%) 4/ 46 (8.7%) 0.47 (0.11, 2.11)
50-80 mL/min 3/ 109 (2.8%) 10/ 116 (8.6%) 0.30 (0.08, 1.09)
>80 mL/min 2/ 45 (4.4%) 6/ 58 (10.3%) 0.45 (0.09, 2.22)
Clopidogrel use with study ASA after randomization
None 7/ 114 (6.1%) 12/ 114 (10.5%) 0.57 (0.22, 1.44) 0.9595
>0 - <=30 days 2/ 63 (3.2%) 7/ 63 (11.1%) 0.28 (0.06, 1.34)
>30 - <=60 days 0/ 16 (0.0%) 1/ 19 (5.3%)
>60 - <=180 days 0/ 24 (0.0%) 3/ 22 (13.6%)
>180 days 0/ 11 (0.0%) 0/ 8 (0.0%)
Atrial fibrillation disease history
No 9/ 224 (4.0%) 22/ 226 (9.7%) 0.40 (0.18, 0.87) 0.9881
Yes 0/ 6 (0.0%) 1/ 3 (33.3%)
Atrial flutter disease history
No 9/ 230 (3.9%) 23/ 229 (10.0%) 0.38 (0.17, 0.81) N/A
Critical limb ischemia
No 6/ 197 (3.0%) 16/ 198 (8.1%) 0.37 (0.14, 0.93) 0.9721
Yes 3/ 33 (9.1%) 7/ 31 (22.6%) 0.36 (0.09, 1.40)
Critical leg ischemia categories
No critical leg ischemia 6/ 197 (3.0%) 16/ 198 (8.1%) 0.37 (0.14, 0.93) 0.6804
Critical leg ischemia history 0/ 15 (0.0%) 4/ 14 (28.6%) 0.85 (0.17, 4.22)
Critical leg ischemia ongoing 3/ 18 (16.7%) 3/ 17 (17.6%)
Length of target lesion on the index leg
SHORT (< 5 CM) 3/ 70 (4.3%) 3/ 56 (5.4%) 0.78 (0.16, 3.88) 0.7100
INTERMEDIATE (5 CM TO < 15 CM) 0/ 73 (0.0%) 4/ 82 (4.9%)
LONG (>= 15 CM) 6/ 87 (6.9%) 16/ 91 (17.6%) 0.35 (0.14, 0.89)
Time from qualifying revasc. procedure to randomization
< Median (Days) 4/ 132 (3.0%) 12/ 120 (10.0%) 0.29 (0.09, 0.91) 0.5232
>= Median (Days) 5/ 98 (5.1%) 11/ 109 (10.1%) 0.47 (0.16, 1.36)
Statin use during study
No 3/ 84 (3.6%) 10/ 84 (11.9%) 0.29 (0.08, 1.07) 0.6184
Yes 6/ 146 (4.1%) 13/ 145 (9.0%) 0.43 (0.16, 1.14)
PAD symptom status (Rutherford score) (<=2, 3, >=4)
<=2 3/ 97 (3.1%) 8/ 107 (7.5%) 0.41 (0.11, 1.55) 0.9766
3 4/ 106 (3.8%) 10/ 98 (10.2%) 0.35 (0.11, 1.13)
>=4 2/ 27 (7.4%) 5/ 24 (20.8%) 0.33 (0.06, 1.68)
PAD symptom status (Rutherford score) (<=2, 3, 4, >=5)
<=2 3/ 97 (3.1%) 8/ 107 (7.5%) 0.41 (0.11, 1.55) 0.9879
3 4/ 106 (3.8%) 10/ 98 (10.2%) 0.35 (0.11, 1.13)
4 2/ 13 (15.4%) 3/ 11 (27.3%) 0.59 (0.10, 3.51)
>= 5 0/ 14 (0.0%) 2/ 13 (15.4%)
0.1
1
10
Favours Riva+ASA
Favours Plac+ASA

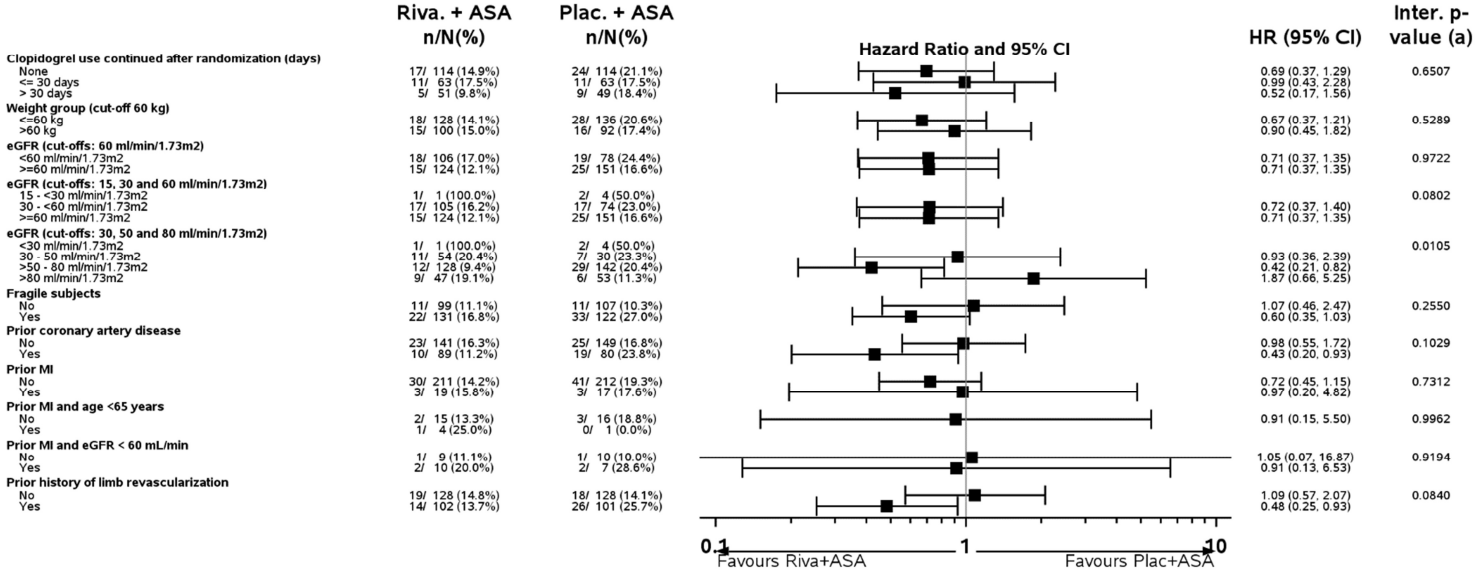


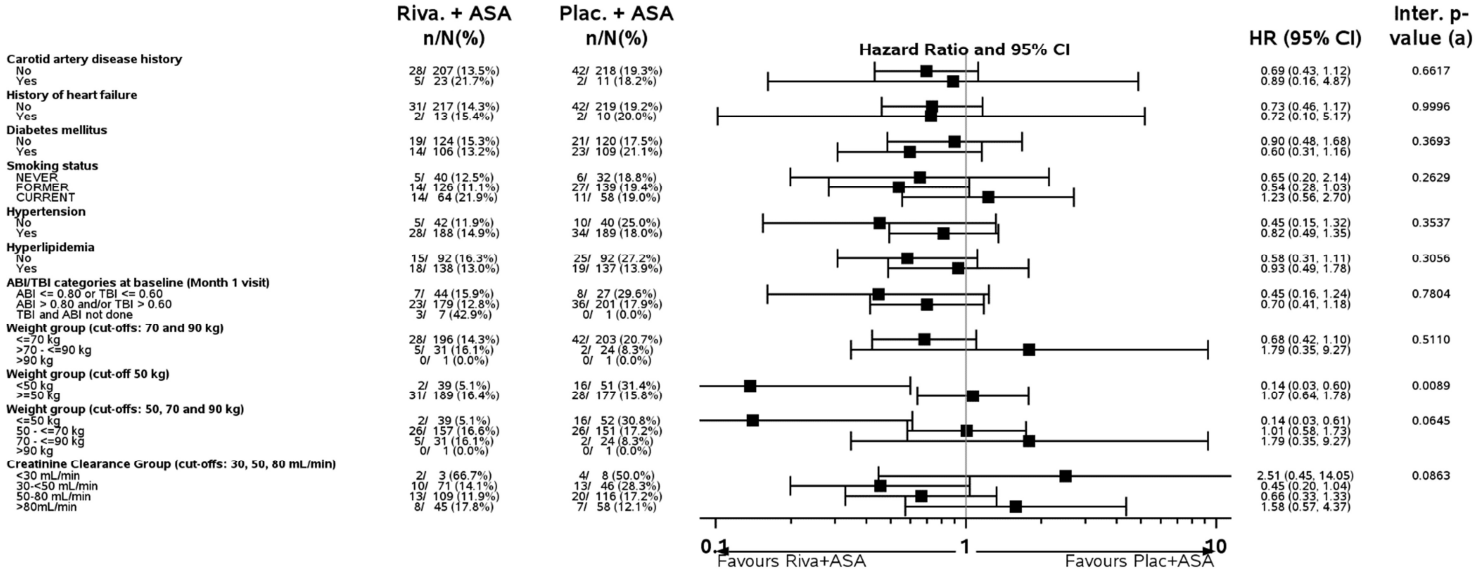
The ITT analysis set includes all randomized subjects. The ITT data scope includes outcome events observed from randomization date until efficacy cut-off date. Subgroup variables from Atrial fibrillation disease history and below are added post-hoc.
MI, stroke, mortality, ALI, major amputation of vascular etiology and events leading to hospitalization are adjudicated by Independent Clinical Adjudication Committee (ICAC), index limb revascularization and venous thromboembolic events are reported by investigator only. Index limb revascularization is defined as subsequent index leg revascularization that was not planned or considered as part of the initial treatment plan at the time of randomization. CV death = Cardiovascular death and unknown cause, MI = Myocardial infarction, ALI = Acute limb ischemia, CHD = coronary heart disease. Efficacy cut-off date = 08SEP2019,
Subjects will be considered fragile if age >75 years or weight <=50 kg or baseline eGFR <50 mL/min/1.73m2.
bid = twice daily, od = once daily, ASA = acetylsalicylic acid, CI = confidence interval, Riva. + ASA = Rivaroxaban 2.5 mg bid + ASA 100 mg od, Plac. + ASA = Rivaroxaban placebo bid + ASA 100 mg od
n = number of subjects with events, N = number of subjects at risk, % = 100 * n/N., Inter. = Interaction
HR (95% CI) is based on the unstratified Cox proportional hazards model, with treatment as the only covariate
(a) P-value for interaction is based on the corresponding Cox proportional hazards model by adding the corresponding treatment interaction term.

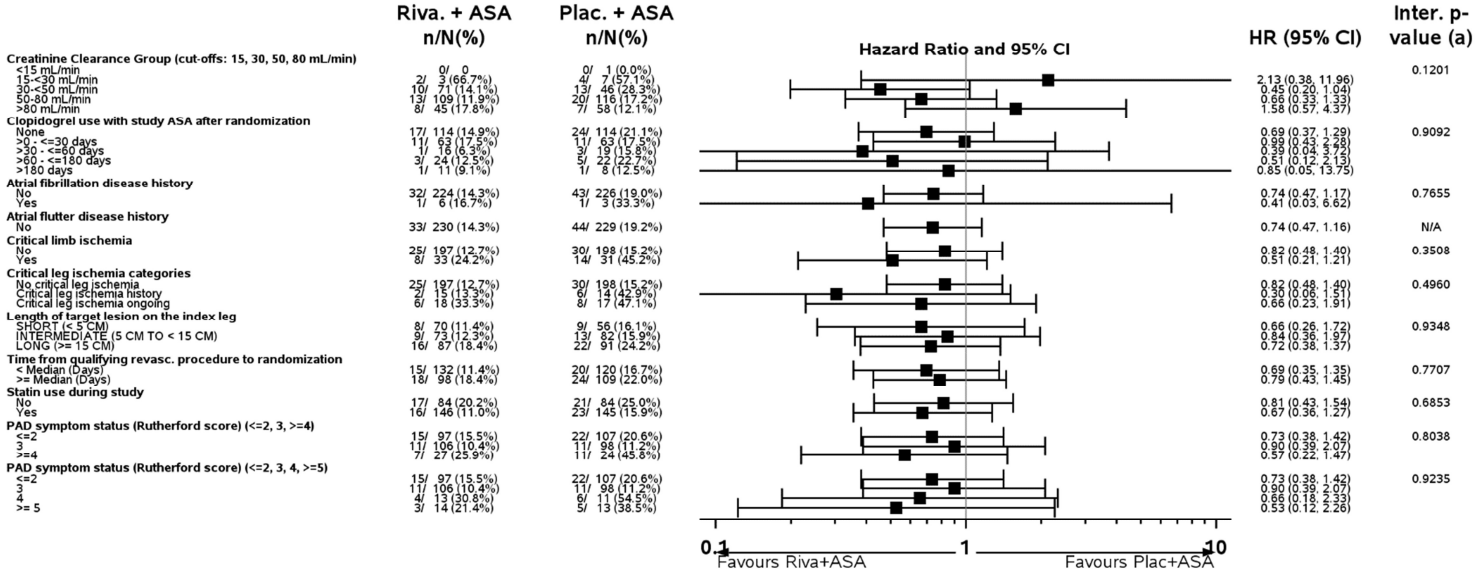
Source: 5.3.5.1.2 17454_J_analysis/Figure 14.2.5.2/31

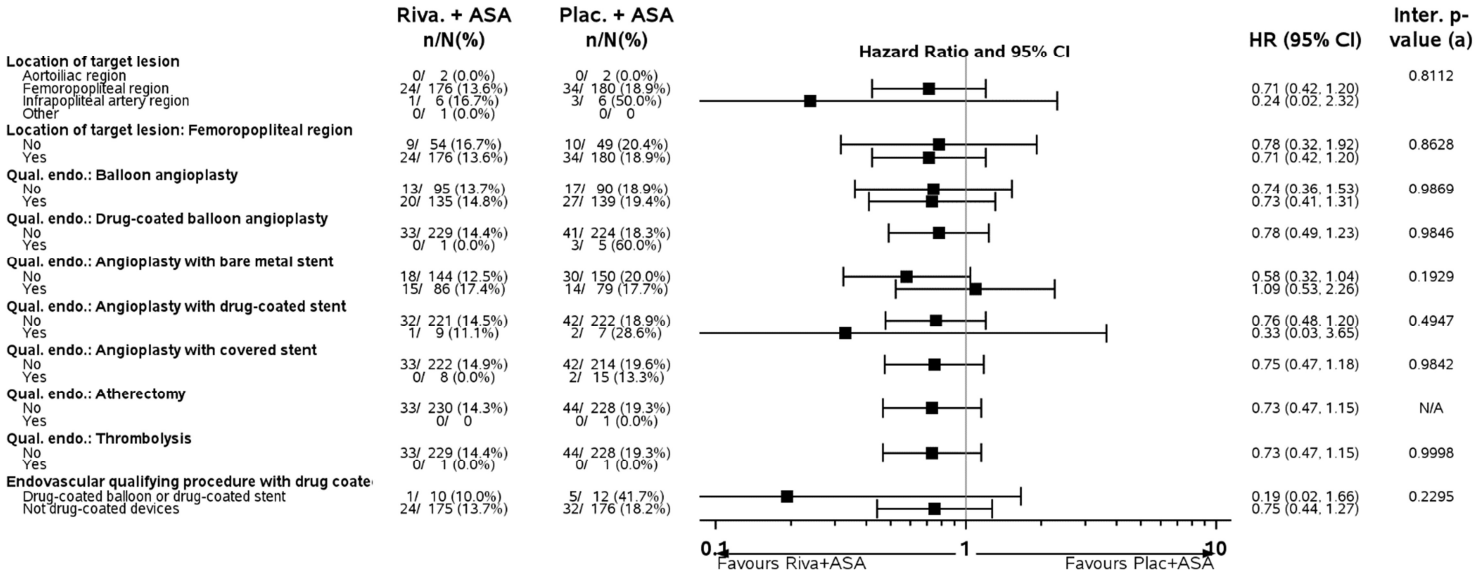
図 2.7.3.7-10 MI、虚血性脳卒中、全死亡、ALI、又は血管系の原因による大切断の複合エンドポイントの Forest プロット（試験 17454、日本人集団、ITT、ECOD まで、ICAC 判定）




Riva. + ASA n/N(%)
Plac. + ASA n/N(%)
Hazard Ratio and 95% CI
HR (95% CI)
Inter. p-value (a)
Clopidogrel use continued after randomization (days)
None 17/ 114 (14.9%) 24/ 114 (21.1%) 0.69 (0.37, 1.29) 0.6507
<= 30 days 11/ 63 (17.5%) 11/ 63 (17.5%) 0.99 (0.43, 2.28)
> 30 days 5/ 51 (9.8%) 9/ 49 (18.4%) 0.52 (0.17, 1.56)
Weight group (cut-off 60 kg)
<=60 kg 18/ 128 (14.1%) 28/ 136 (20.6%) 0.67 (0.37, 1.21) 0.5289
>60 kg 15/ 100 (15.0%) 16/ 92 (17.4%) 0.90 (0.45, 1.82)
eGFR (cut-offs: 60 ml/min/1.73m2)
<60 ml/min/1.73m2 18/ 106 (17.0%) 19/ 78 (24.4%) 0.71 (0.37, 1.35) 0.9722
>=60 ml/min/1.73m2 15/ 124 (12.1%) 25/ 151 (16.6%) 0.71 (0.37, 1.35)
eGFR (cut-offs: 15, 30 and 60 ml/min/1.73m2)
15 - <30 ml/min/1.73m2 1/ 1 (100.0%) 2/ 4 (50.0%) 0.0802
30 - <60 ml/min/1.73m2 17/ 105 (16.2%) 17/ 74 (23.0%) 0.72 (0.37, 1.40)
>=60 ml/min/1.73m2 15/ 124 (12.1%) 25/ 151 (16.6%) 0.71 (0.37, 1.35)
eGFR (cut-offs: 30, 50 and 80 ml/min/1.73m2)
<30 ml/min/1.73m2 1/ 1 (100.0%) 2/ 4 (50.0%) 0.0105
30 - 50 ml/min/1.73m2 11/ 54 (20.4%) 7/ 30 (23.3%) 0.93 (0.36, 2.39)
>50 - 80 ml/min/1.73m2 12/ 128 (9.4%) 29/ 142 (20.4%) 0.42 (0.21, 0.82)
>80 ml/min/1.73m2 9/ 47 (19.1%) 6/ 53 (11.3%) 1.87 (0.66, 5.25)
Fragile subjects
No 11/ 99 (11.1%) 11/ 107 (10.3%) 1.07 (0.46, 2.47) 0.2550
Yes 22/ 131 (16.8%) 33/ 122 (27.0%) 0.60 (0.35, 1.03)
Prior coronary artery disease
No 23/ 141 (16.3%) 25/ 149 (16.8%) 0.98 (0.55, 1.72) 0.1029
Yes 10/ 89 (11.2%) 19/ 80 (23.8%) 0.43 (0.20, 0.93)
Prior MI
No 30/ 211 (14.2%) 41/ 212 (19.3%) 0.72 (0.45, 1.15) 0.7312
Yes 3/ 19 (15.8%) 3/ 17 (17.6%) 0.97 (0.20, 4.82)
Prior MI and age <65 years
No 2/ 15 (13.3%) 3/ 16 (18.8%) 0.91 (0.15, 5.50) 0.9962
Yes 1/ 4 (25.0%) 0/ 1 (0.0%)
Prior MI and eGFR < 60 mL/min
No 1/ 9 (11.1%) 1/ 10 (10.0%) 1.05 (0.07, 16.87) 0.9194
Yes 2/ 10 (20.0%) 2/ 7 (28.6%) 0.91 (0.13, 6.53)
Prior history of limb revascularization
No 19/ 128 (14.8%) 18/ 128 (14.1%) 1.09 (0.57, 2.07) 0.0840
Yes 14/ 102 (13.7%) 26/ 101 (25.7%) 0.48 (0.25, 0.93)
0.1
1
10
Favours Riva+ASA
Favours Plac+ASA


Riva. + ASA n/N(%)
Plac. + ASA n/N(%)
Hazard Ratio and 95% CI
HR (95% CI)
Inter. p-value (a)
Carotid artery disease history
No 28/ 207 (13.5%) 42/ 218 (19.3%) 0.69 (0.43, 1.12) 0.6617
Yes 5/ 23 (21.7%) 2/ 11 (18.2%) 0.89 (0.16, 4.87)
History of heart failure
No 31/ 217 (14.3%) 42/ 219 (19.2%) 0.73 (0.46, 1.17) 0.9996
Yes 2/ 13 (15.4%) 2/ 10 (20.0%) 0.72 (0.10, 5.17)
Diabetes mellitus
No 19/ 124 (15.3%) 21/ 120 (17.5%) 0.90 (0.48, 1.68) 0.3693
Yes 14/ 106 (13.2%) 23/ 109 (21.1%) 0.60 (0.31, 1.16)
Smoking status
NEVER 5/ 40 (12.5%) 6/ 32 (18.8%) 0.65 (0.20, 2.14) 0.2629
FORMER 14/ 126 (11.1%) 27/ 139 (19.4%) 0.54 (0.28, 1.03)
CURRENT 14/ 64 (21.9%) 11/ 58 (19.0%) 1.23 (0.56, 2.70)
Hypertension
No 5/ 42 (11.9%) 10/ 40 (25.0%) 0.45 (0.15, 1.32) 0.3537
Yes 28/ 188 (14.9%) 34/ 189 (18.0%) 0.82 (0.49, 1.35)
Hyperlipidemia
No 15/ 92 (16.3%) 25/ 92 (27.2%) 0.58 (0.31, 1.11) 0.3056
Yes 18/ 138 (13.0%) 19/ 137 (13.9%) 0.93 (0.49, 1.78)
ABI/TBI categories at baseline (Month 1 visit)
ABI <= 0.80 or TBI <= 0.60 7/ 44 (15.9%) 8/ 27 (29.6%) 0.45 (0.16, 1.24) 0.7804
ABI > 0.80 and/or TBI > 0.60 23/ 179 (12.8%) 36/ 201 (17.9%) 0.70 (0.41, 1.18)
TBI and ABI not done 3/ 7 (42.9%) 0/ 1 (0.0%)
Weight group (cut-offs: 70 and 90 kg)
<=70 kg 28/ 196 (14.3%) 42/ 203 (20.7%) 0.68 (0.42, 1.10) 0.5110
>70 - <=90 kg 5/ 31 (16.1%) 2/ 24 (8.3%) 1.79 (0.35, 9.27)
>90 kg 0/ 1 (0.0%) 0/ 1 (0.0%)
Weight group (cut-off 50 kg)
<50 kg 2/ 39 (5.1%) 16/ 51 (31.4%) 0.14 (0.03, 0.60) 0.0089
>=50 kg 31/ 189 (16.4%) 28/ 177 (15.8%) 1.07 (0.64, 1.78)
Weight group (cut-offs: 50, 70 and 90 kg)
<=50 kg 2/ 39 (5.1%) 16/ 52 (30.8%) 0.14 (0.03, 0.61) 0.0645
50 - <=70 kg 26/ 157 (16.6%) 26/ 151 (17.2%) 1.01 (0.58, 1.73)
70 - <=90 kg 5/ 31 (16.1%) 2/ 24 (8.3%) 1.79 (0.35, 9.27)
>90 kg 0/ 1 (0.0%) 0/ 1 (0.0%)
Creatinine Clearance Group (cut-offs: 30, 50, 80 mL/min)
<30 mL/min 2/ 3 (66.7%) 4/ 8 (50.0%) 2.51 (0.45, 14.05) 0.0863
30-<50 mL/min 10/ 71 (14.1%) 13/ 46 (28.3%) 0.45 (0.20, 1.04)
50-80 mL/min 13/ 109 (11.9%) 20/ 116 (17.2%) 0.66 (0.33, 1.33)
>80mL/min 8/ 45 (17.8%) 7/ 58 (12.1%) 1.58 (0.57, 4.37)
0.1
1
10
Favours Riva+ASA
Favours Plac+ASA


Riva. + ASA n/N(%)
Plac. + ASA n/N(%)
Hazard Ratio and 95% CI
HR (95% CI)
Inter. p-value (a)
Creatinine Clearance Group (cut-offs: 15, 30, 50, 80 mL/min)
<15 mL/min 0/ 0 0/ 1 (0.0%) 0.1201
15-<30 mL/min 2/ 3 (66.7%) 4/ 7 (57.1%) 2.13 (0.38, 11.96)
30-<50 mL/min 10/ 71 (14.1%) 13/ 46 (28.3%) 0.45 (0.20, 1.04)
50-80 mL/min 13/ 109 (11.9%) 20/ 116 (17.2%) 0.66 (0.33, 1.33)
>80 mL/min 8/ 45 (17.8%) 7/ 58 (12.1%) 1.58 (0.57, 4.37)
Clopidogrel use with study ASA after randomization
None 17/ 114 (14.9%) 24/ 114 (21.1%) 0.69 (0.37, 1.29) 0.9092
>0 - <=30 days 11/ 63 (17.5%) 11/ 63 (17.5%) 0.99 (0.43, 2.28)
>30 - <=60 days 1/ 16 (6.3%) 3/ 19 (15.8%) 0.39 (0.04, 3.72)
>60 - <=180 days 3/ 24 (12.5%) 5/ 22 (22.7%) 0.51 (0.12, 2.13)
>180 days 1/ 11 (9.1%) 1/ 8 (12.5%) 0.85 (0.05, 13.75)
Atrial fibrillation disease history
No 32/ 224 (14.3%) 43/ 226 (19.0%) 0.74 (0.47, 1.17) 0.7655
Yes 1/ 6 (16.7%) 1/ 3 (33.3%) 0.41 (0.03, 6.62)
Atrial flutter disease history
No 33/ 230 (14.3%) 44/ 229 (19.2%) 0.74 (0.47, 1.16) N/A
Critical limb ischemia
No 25/ 197 (12.7%) 30/ 198 (15.2%) 0.82 (0.48, 1.40) 0.3508
Yes 8/ 33 (24.2%) 14/ 31 (45.2%) 0.51 (0.21, 1.21)
Critical leg ischemia categories
No critical leg ischemia 25/ 197 (12.7%) 30/ 198 (15.2%) 0.82 (0.48, 1.40) 0.4960
Critical leg ischemia history 2/ 15 (13.3%) 6/ 14 (42.9%) 0.30 (0.06, 1.51)
Critical leg ischemia ongoing 6/ 18 (33.3%) 8/ 17 (47.1%) 0.66 (0.23, 1.91)
Length of target lesion on the index leg
SHORT (< 5 CM) 8/ 70 (11.4%) 9/ 56 (16.1%) 0.66 (0.26, 1.72) 0.9348
INTERMEDIATE (5 CM TO < 15 CM) 9/ 73 (12.3%) 13/ 82 (15.9%) 0.84 (0.36, 1.97)
LONG (>= 15 CM) 16/ 87 (18.4%) 22/ 91 (24.2%) 0.72 (0.38, 1.37)
Time from qualifying revasc. procedure to randomization
< Median (Days) 15/ 132 (11.4%) 20/ 120 (16.7%) 0.69 (0.35, 1.35) 0.7707
>= Median (Days) 18/ 98 (18.4%) 24/ 109 (22.0%) 0.79 (0.43, 1.45)
Statin use during study
No 17/ 84 (20.2%) 21/ 84 (25.0%) 0.81 (0.43, 1.54) 0.6853
Yes 16/ 146 (11.0%) 23/ 145 (15.9%) 0.67 (0.36, 1.27)
PAD symptom status (Rutherford score) (<=2, 3, >=4)
<=2 15/ 97 (15.5%) 22/ 107 (20.6%) 0.73 (0.38, 1.42) 0.8038
3 11/ 106 (10.4%) 11/ 98 (11.2%) 0.90 (0.39, 2.07)
>=4 7/ 27 (25.9%) 11/ 24 (45.8%) 0.57 (0.22, 1.47)
PAD symptom status (Rutherford score) (<=2, 3, 4, >=5)
<=2 15/ 97 (15.5%) 22/ 107 (20.6%) 0.73 (0.38, 1.42) 0.9235
3 11/ 106 (10.4%) 11/ 98 (11.2%) 0.90 (0.39, 2.07)
4 4/ 13 (30.8%) 6/ 11 (54.5%) 0.66 (0.18, 2.33)
>= 5 3/ 14 (21.4%) 5/ 13 (38.5%) 0.53 (0.12, 2.26)
0.1
1
10
Favours Riva+ASA
Favours Plac+ASA



The ITT analysis set includes all randomized subjects. The ITT data scope includes outcome events observed from randomization date until efficacy cut-off date. Subgroup variables from Atrial fibrillation disease history and below are added post-hoc.
MI, stroke, mortality, ALI, major amputation of vascular etiology and events leading to hospitalization are adjudicated by Independent Clinical Adjudication Committee (ICAC), index limb revascularization and venous thromboembolic events are reported by investigator only. Index limb revascularization is defined as subsequent index leg revascularization that was not planned or considered as part of the initial treatment plan at the time of randomization. CV death = Cardiovascular death and unknown cause, MI = Myocardial infarction, ALI = Acute limb ischemia, CHD = coronary heart disease. Efficacy cut-off date = 08SEP2019,
Subjects will be considered fragile if age >75 years or weight <=50 kg or baseline eGFR <50 mL/min/1.73m2.
bid = twice daily, od = once daily, ASA = acetylsalicylic acid, CI = confidence interval, Riva. + ASA = Rivaroxaban 2.5 mg bid + ASA 100 mg od, Plac. + ASA = Rivaroxaban placebo bid + ASA 100 mg od
n = number of subjects with events, N = number of subjects at risk, % = 100 * n/N., Inter. = Interaction
HR (95% CI) is based on the unstratified Cox proportional hazards model, with treatment as the only covariate
(a) P-value for interaction is based on the corresponding Cox proportional hazards model by adding the corresponding treatment interaction term.

Source: 5.3.5.1.2 17454_J_analysis/Figure 14.2.5.2/40