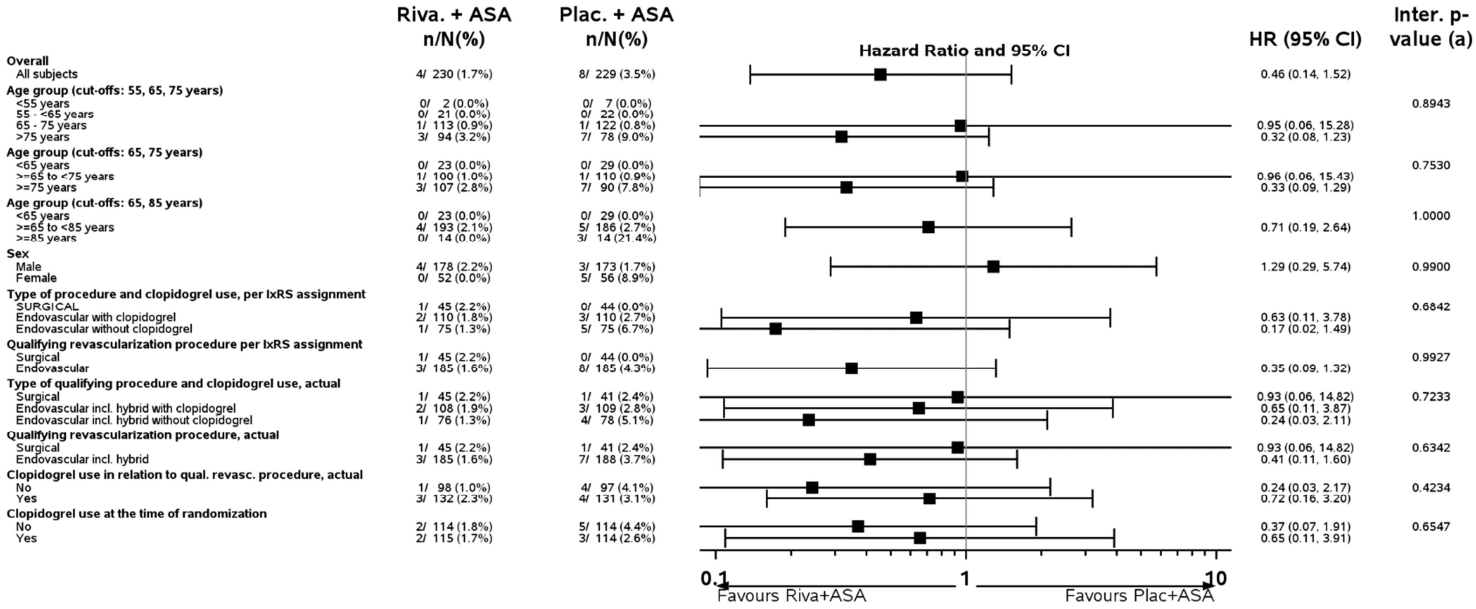
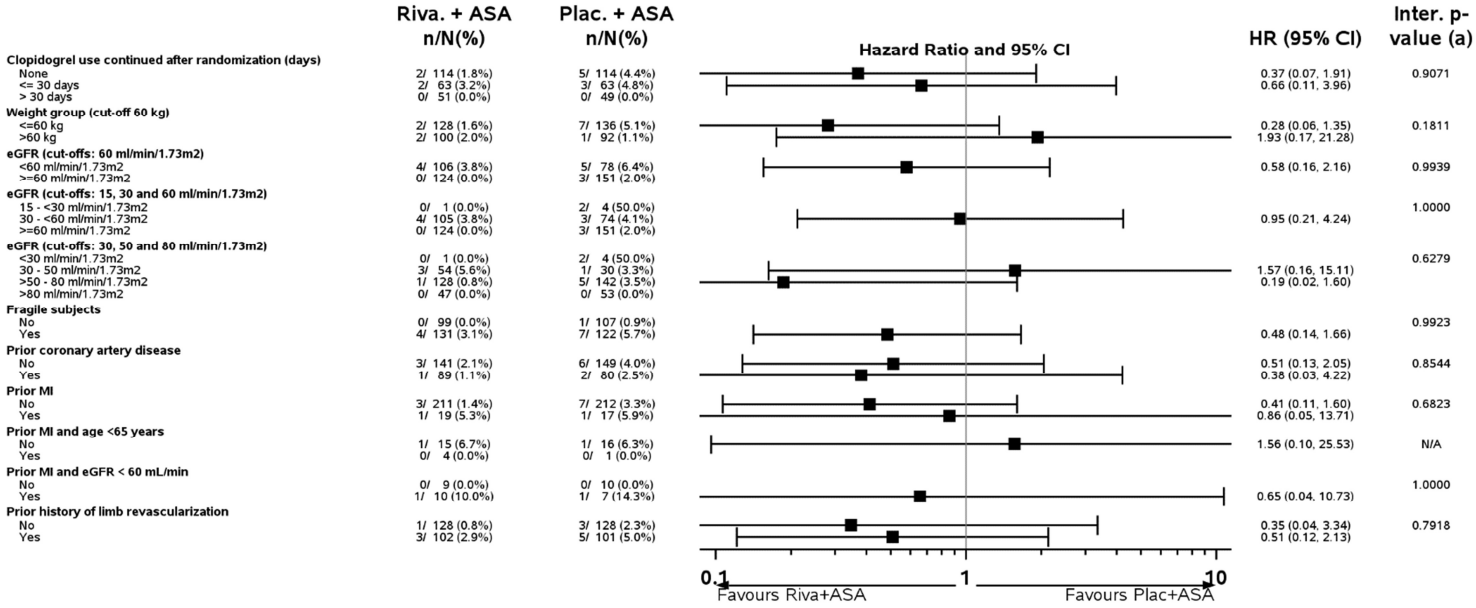
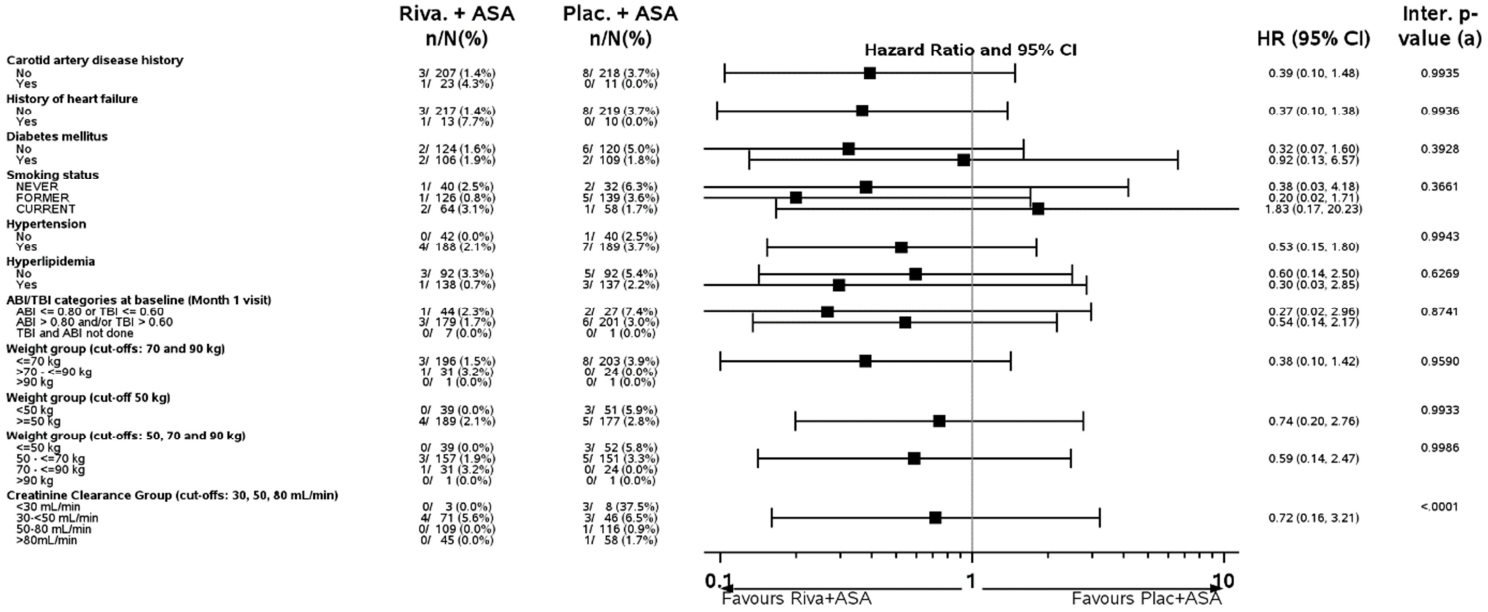
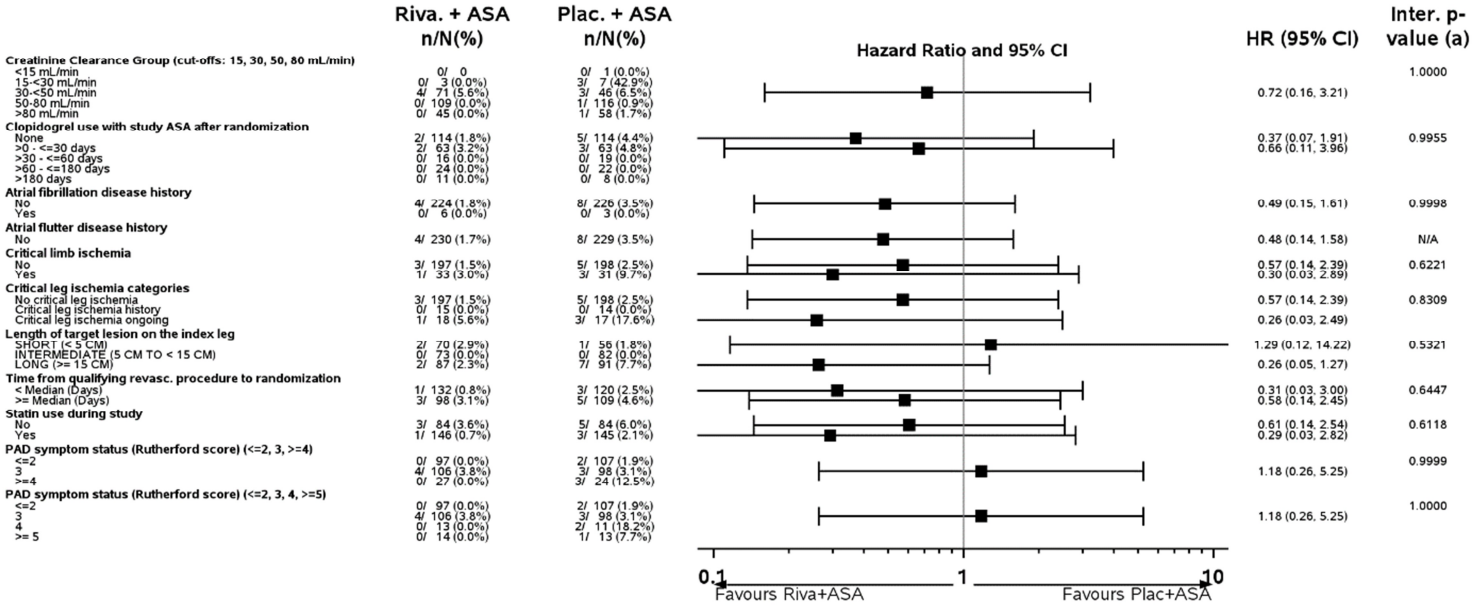
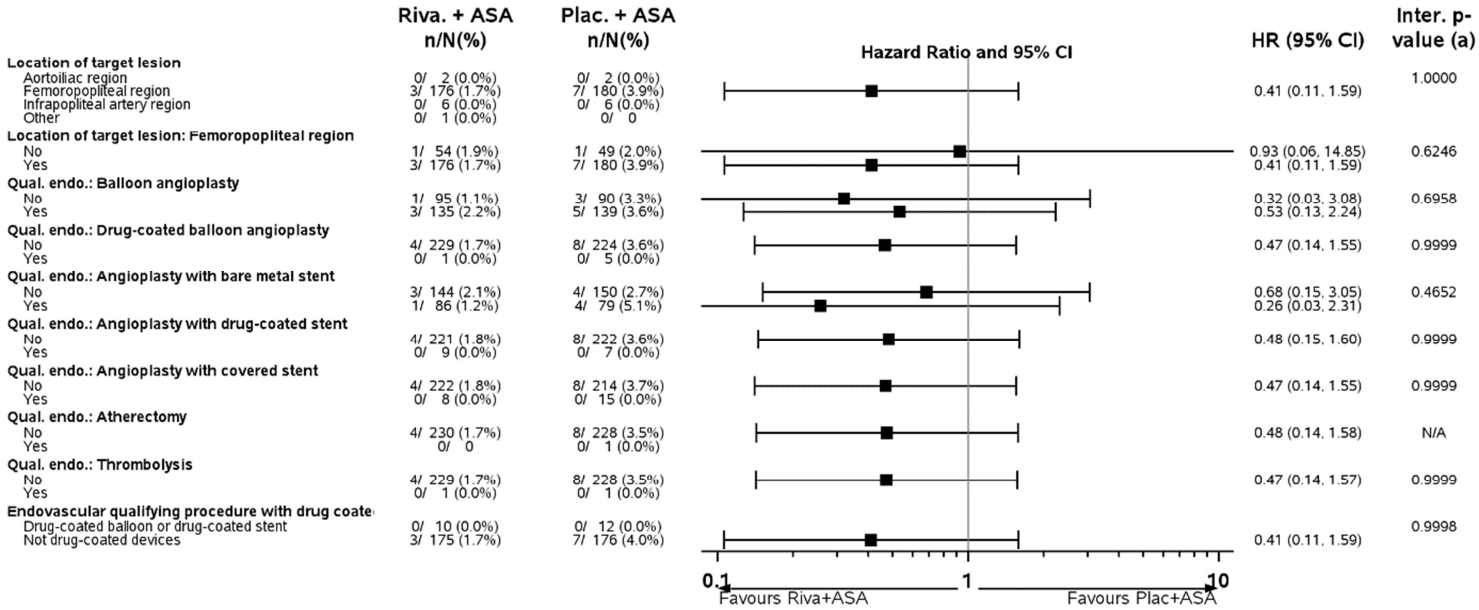
図 2.7.3.7-16 心血管死の Forest プロット（試験 17454、日本人集団、ITT、ECOD まで、ICAC 判定）




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 2/ 114 (1.8%) 5/ 114 (4.4%) 0.37 (0.07, 1.91) 0.9071
<= 30 days 2/ 63 (3.2%) 3/ 63 (4.8%) 0.66 (0.11, 3.96)
> 30 days 0/ 51 (0.0%) 0/ 49 (0.0%)
Weight group (cut-off 60 kg)
<=60 kg 2/ 128 (1.6%) 7/ 136 (5.1%) 0.28 (0.06, 1.35) 0.1811
>60 kg 2/ 100 (2.0%) 1/ 92 (1.1%) 1.93 (0.17, 21.28)
eGFR (cut-offs: 60 ml/min/1.73m2)
<60 ml/min/1.73m2 4/ 106 (3.8%) 5/ 78 (6.4%) 0.58 (0.16, 2.16) 0.9939
>=60 ml/min/1.73m2 0/ 124 (0.0%) 3/ 151 (2.0%)
eGFR (cut-offs: 15, 30 and 60 ml/min/1.73m2)
15 - <30 ml/min/1.73m2 0/ 1 (0.0%) 2/ 4 (50.0%) 1.0000
30 - <60 ml/min/1.73m2 4/ 105 (3.8%) 3/ 74 (4.1%) 0.95 (0.21, 4.24)
>=60 ml/min/1.73m2 0/ 124 (0.0%) 3/ 151 (2.0%)
eGFR (cut-offs: 30, 50 and 80 ml/min/1.73m2)
<30 ml/min/1.73m2 0/ 1 (0.0%) 2/ 4 (50.0%) 0.6279
30 - 50 ml/min/1.73m2 3/ 54 (5.6%) 1/ 30 (3.3%) 1.57 (0.16, 15.11)
>50 - 80 ml/min/1.73m2 1/ 128 (0.8%) 5/ 142 (3.5%) 0.19 (0.02, 1.60)
>80 ml/min/1.73m2 0/ 47 (0.0%) 0/ 53 (0.0%)
Fragile subjects
No 0/ 99 (0.0%) 1/ 107 (0.9%) 0.9923
Yes 4/ 131 (3.1%) 7/ 122 (5.7%) 0.48 (0.14, 1.66)
Prior coronary artery disease
No 3/ 141 (2.1%) 6/ 149 (4.0%) 0.51 (0.13, 2.05) 0.8544
Yes 1/ 89 (1.1%) 2/ 80 (2.5%) 0.38 (0.03, 4.22)
Prior MI
No 3/ 211 (1.4%) 7/ 212 (3.3%) 0.41 (0.11, 1.60) 0.6823
Yes 1/ 19 (5.3%) 1/ 17 (5.9%) 0.86 (0.05, 13.71)
Prior MI and age <65 years
No 1/ 15 (6.7%) 1/ 16 (6.3%) 1.56 (0.10, 25.53) 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%) 1.0000
Yes 1/ 10 (10.0%) 1/ 7 (14.3%) 0.65 (0.04, 10.73)
Prior history of limb revascularization
No 1/ 128 (0.8%) 3/ 128 (2.3%) 0.35 (0.04, 3.34) 0.7918
Yes 3/ 102 (2.9%) 5/ 101 (5.0%) 0.51 (0.12, 2.13)
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 3/ 207 (1.4%) 8/ 218 (3.7%) 0.39 (0.10, 1.48) 0.9935
Yes 1/ 23 (4.3%) 0/ 11 (0.0%)
History of heart failure
No 3/ 217 (1.4%) 8/ 219 (3.7%) 0.37 (0.10, 1.38) 0.9936
Yes 1/ 13 (7.7%) 0/ 10 (0.0%)
Diabetes mellitus
No 2/ 124 (1.6%) 6/ 120 (5.0%) 0.32 (0.07, 1.60) 0.3928
Yes 2/ 106 (1.9%) 2/ 109 (1.8%) 0.92 (0.13, 6.57)
Smoking status
NEVER 1/ 40 (2.5%) 2/ 32 (6.3%) 0.38 (0.03, 4.18) 0.3661
FORMER 1/ 126 (0.8%) 5/ 139 (3.6%) 0.20 (0.02, 1.71)
CURRENT 2/ 64 (3.1%) 1/ 58 (1.7%) 1.83 (0.17, 20.23)
Hypertension
No 0/ 42 (0.0%) 1/ 40 (2.5%) 0.9943
Yes 4/ 188 (2.1%) 7/ 189 (3.7%) 0.53 (0.15, 1.80)
Hyperlipidemia
No 3/ 92 (3.3%) 5/ 92 (5.4%) 0.60 (0.14, 2.50) 0.6269
Yes 1/ 138 (0.7%) 3/ 137 (2.2%) 0.30 (0.03, 2.85)
ABI/TBI categories at baseline (Month 1 visit)
ABI <= 0.80 or TBI <= 0.60 1/ 44 (2.3%) 2/ 27 (7.4%) 0.27 (0.02, 2.96) 0.8741
ABI > 0.80 and/or TBI > 0.60 3/ 179 (1.7%) 6/ 201 (3.0%) 0.54 (0.14, 2.17)
TBI and ABI not done 0/ 7 (0.0%) 0/ 1 (0.0%)
Weight group (cut-offs: 70 and 90 kg)
<=70 kg 3/ 196 (1.5%) 8/ 203 (3.9%) 0.38 (0.10, 1.42) 0.9590
>70 - <=90 kg 1/ 31 (3.2%) 0/ 24 (0.0%)
>90 kg 0/ 1 (0.0%) 0/ 1 (0.0%)
Weight group (cut-off 50 kg)
<50 kg 0/ 39 (0.0%) 3/ 51 (5.9%) 0.9933
>=50 kg 4/ 189 (2.1%) 5/ 177 (2.8%) 0.74 (0.20, 2.76)
Weight group (cut-offs: 50, 70 and 90 kg)
<=50 kg 0/ 39 (0.0%) 3/ 52 (5.8%) 0.9986
50 - <=70 kg 3/ 157 (1.9%) 5/ 151 (3.3%) 0.59 (0.14, 2.47)
70 - <=90 kg 1/ 31 (3.2%) 0/ 24 (0.0%)
>90 kg 0/ 1 (0.0%) 0/ 1 (0.0%)
Creatinine Clearance Group (cut-offs: 30, 50, 80 mL/min)
<30 mL/min 0/ 3 (0.0%) 3/ 8 (37.5%) <.0001
30-<50 mL/min 4/ 71 (5.6%) 3/ 46 (6.5%) 0.72 (0.16, 3.21)
50-80 mL/min 0/ 109 (0.0%) 1/ 116 (0.9%)
>80mL/min 0/ 45 (0.0%) 1/ 58 (1.7%)
0.1
1
10
Favours Riva+ASA
Favours Plac+ASA

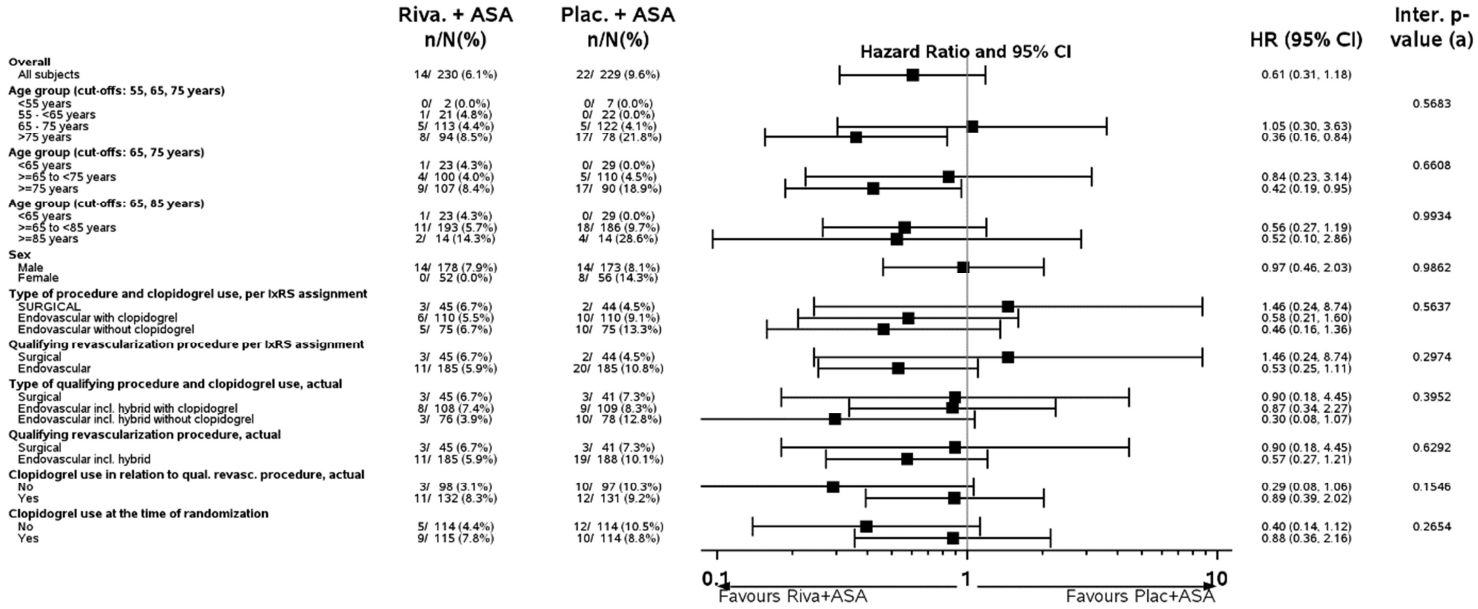

Riva. + ASA n/N(%)
Plac. + ASA n/N(%)
Hazard Ratio and 95% CI
HR (95% CI)
Inter. p-value (a)
Creatinine Clearance Group (cut-offs: 15, 30, 50, 80 mL/min)
<15 mL/min 0/ 0 0/ 1 (0.0%) 1.0000
15-<30 mL/min 0/ 3 (0.0%) 3/ 7 (42.9%) 0.72 (0.16, 3.21)
30-<50 mL/min 4/ 71 (5.6%) 3/ 46 (6.5%)
50-80 mL/min 0/ 109 (0.0%) 1/ 116 (0.9%)
>80 mL/min 0/ 45 (0.0%) 1/ 58 (1.7%)
Clopidogrel use with study ASA after randomization
None 2/ 114 (1.8%) 5/ 114 (4.4%) 0.37 (0.07, 1.91) 0.9955
>0 - <=30 days 2/ 63 (3.2%) 3/ 63 (4.8%) 0.66 (0.11, 3.96)
>30 - <=60 days 0/ 16 (0.0%) 0/ 19 (0.0%)
>60 - <=180 days 0/ 24 (0.0%) 0/ 22 (0.0%)
>180 days 0/ 11 (0.0%) 0/ 8 (0.0%)
Atrial fibrillation disease history
No 4/ 224 (1.8%) 8/ 226 (3.5%) 0.49 (0.15, 1.61) 0.9998
Yes 0/ 6 (0.0%) 0/ 3 (0.0%)
Atrial flutter disease history
No 4/ 230 (1.7%) 8/ 229 (3.5%) 0.48 (0.14, 1.58) N/A
Critical limb ischemia
No 3/ 197 (1.5%) 5/ 198 (2.5%) 0.57 (0.14, 2.39) 0.6221
Yes 1/ 33 (3.0%) 3/ 31 (9.7%) 0.30 (0.03, 2.89)
Critical leg ischemia categories
No critical leg ischemia 3/ 197 (1.5%) 5/ 198 (2.5%) 0.57 (0.14, 2.39) 0.8309
Critical leg ischemia history 0/ 15 (0.0%) 0/ 14 (0.0%)
Critical leg ischemia ongoing 1/ 18 (5.6%) 3/ 17 (17.6%) 0.26 (0.03, 2.49)
Length of target lesion on the index leg
SHORT (< 5 CM) 2/ 70 (2.9%) 1/ 56 (1.8%) 1.29 (0.12, 14.22) 0.5321
INTERMEDIATE (5 CM TO < 15 CM) 0/ 73 (0.0%) 0/ 82 (0.0%)
LONG (>= 15 CM) 2/ 87 (2.3%) 7/ 91 (7.7%) 0.26 (0.05, 1.27)
Time from qualifying revasc. procedure to randomization
< Median (Days) 1/ 132 (0.8%) 3/ 120 (2.5%) 0.31 (0.03, 3.00) 0.6447
>= Median (Days) 3/ 98 (3.1%) 5/ 109 (4.6%) 0.58 (0.14, 2.45)
Statin use during study
No 3/ 84 (3.6%) 5/ 84 (6.0%) 0.61 (0.14, 2.54) 0.6118
Yes 1/ 146 (0.7%) 3/ 145 (2.1%) 0.29 (0.03, 2.82)
PAD symptom status (Rutherford score) (<=2, 3, >=4)
<=2 0/ 97 (0.0%) 2/ 107 (1.9%) 0.9999
3 4/ 106 (3.8%) 3/ 98 (3.1%) 1.18 (0.26, 5.25)
>=4 0/ 27 (0.0%) 3/ 24 (12.5%)
PAD symptom status (Rutherford score) (<=2, 3, 4, >=5)
<=2 0/ 97 (0.0%) 2/ 107 (1.9%) 1.0000
3 4/ 106 (3.8%) 3/ 98 (3.1%) 1.18 (0.26, 5.25)
4 0/ 13 (0.0%) 2/ 11 (18.2%)
>= 5 0/ 14 (0.0%) 1/ 13 (7.7%)
0.1
1
10
Favours Riva+ASA
Favours Plac+ASA

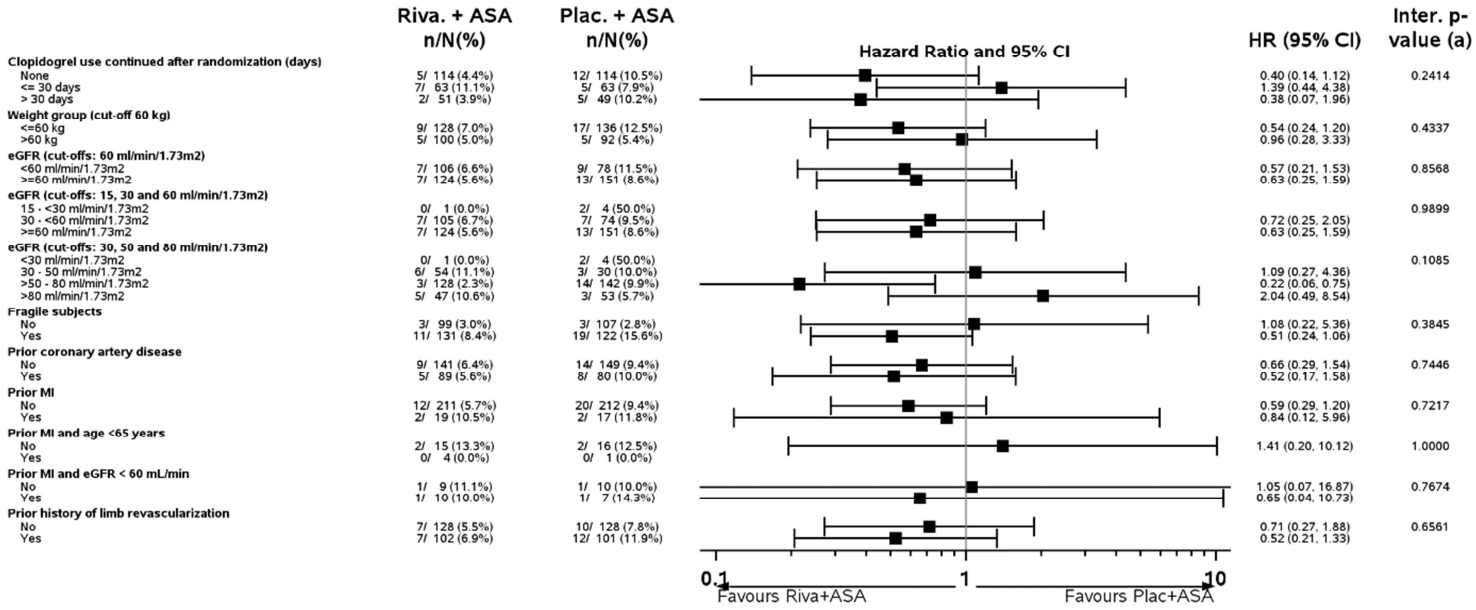


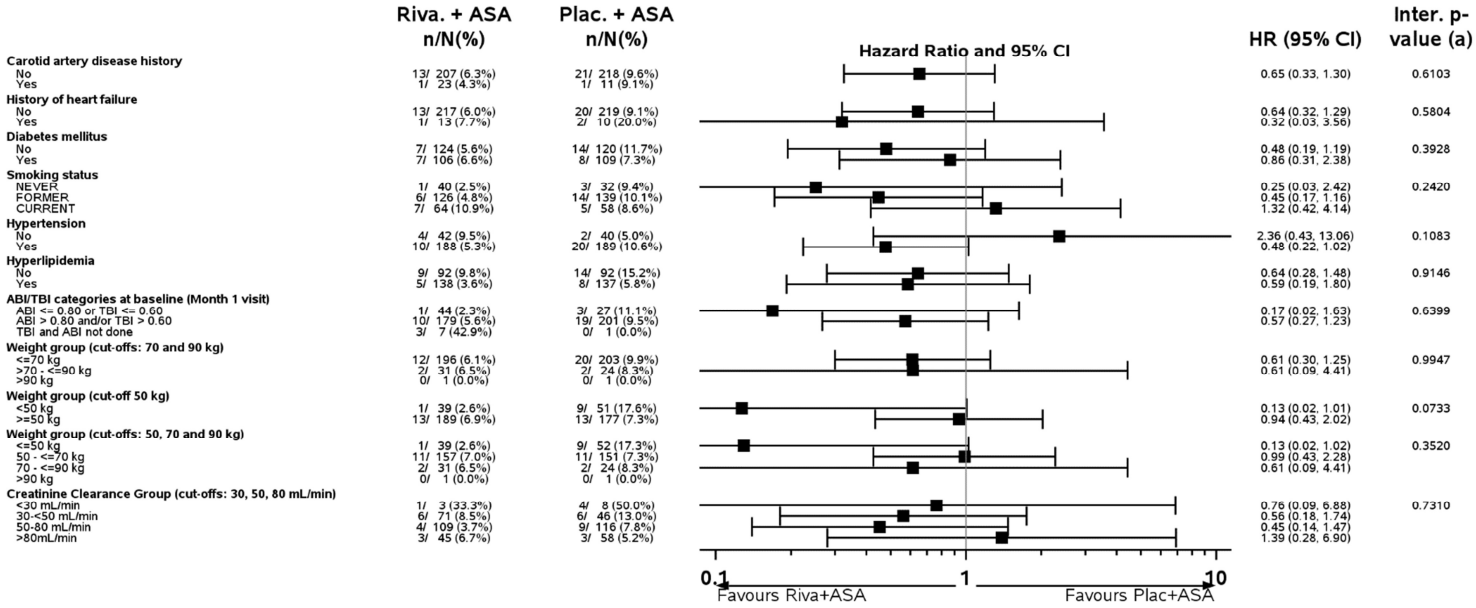
The ITT analysis set includes all randomized subjects. The ITT data scope includes outcome events observed from randomization date until efficacy cut-off date. Subgroup variables from Atrial fibrillation disease history and below are added post-hoc.
MI, stroke, mortality, ALI, major amputation of vascular 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.

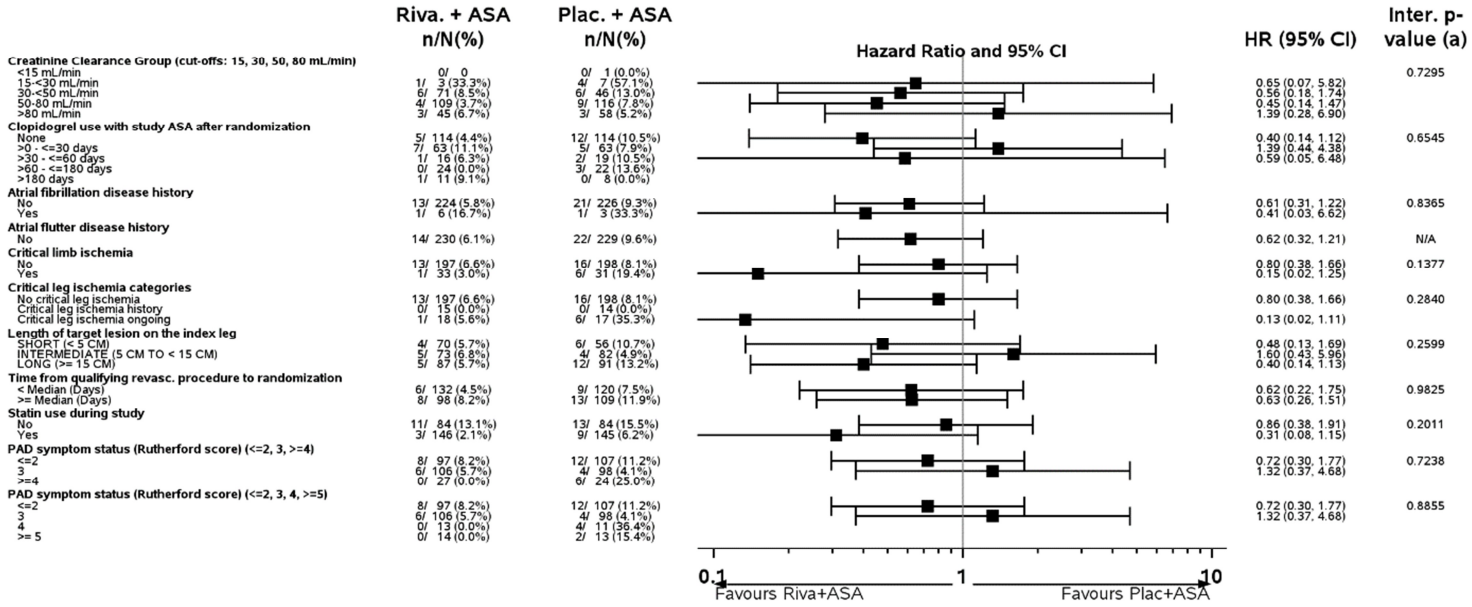
Source: 5.3.5.1.2 17454_J_analysis/Figure 14.2.5.2/76

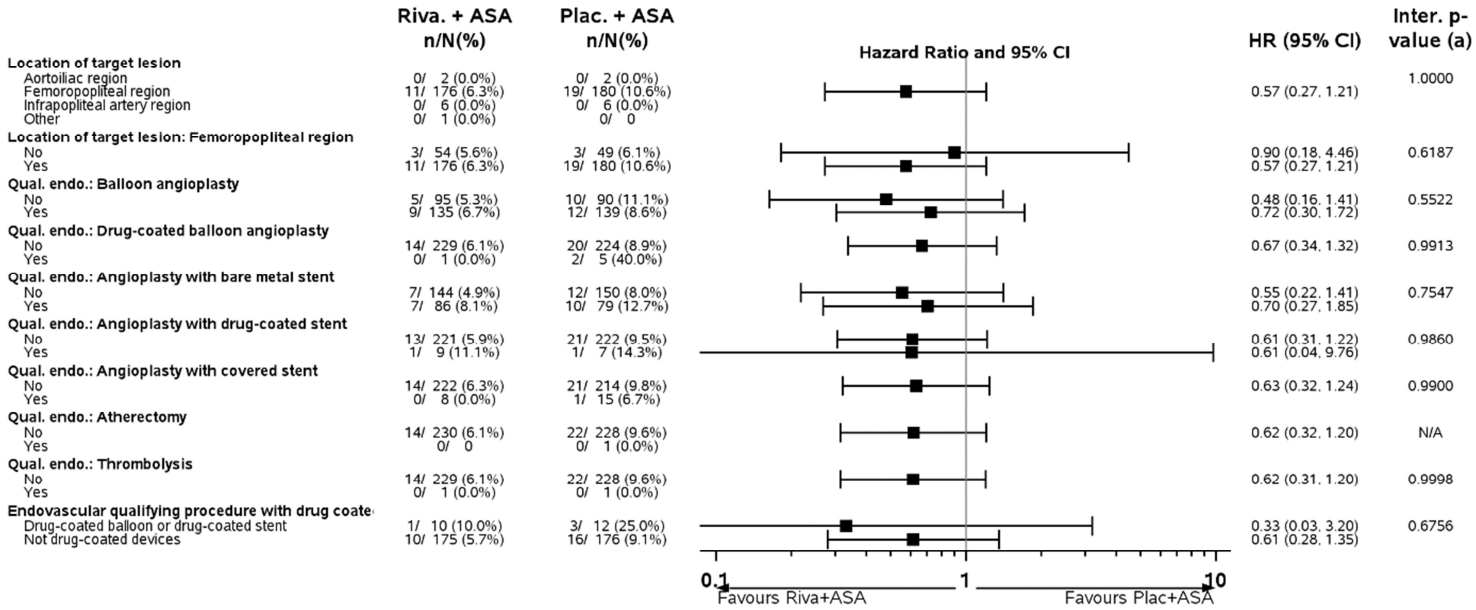
図 2.7.3.7-17　全死亡の Forest プロット（試験 17454、日本人集団、ITT、ECOD まで、ICAC 判定）




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 5/ 114 (4.4%) 12/ 114 (10.5%) 0.40 (0.14, 1.12) 0.2414
<= 30 days 7/ 63 (11.1%) 5/ 63 (7.9%) 1.39 (0.44, 4.38)
> 30 days 2/ 51 (3.9%) 5/ 49 (10.2%) 0.38 (0.07, 1.96)
Weight group (cut-off 60 kg)
<=60 kg 9/ 128 (7.0%) 17/ 136 (12.5%) 0.54 (0.24, 1.20) 0.4337
>60 kg 5/ 100 (5.0%) 5/ 92 (5.4%) 0.96 (0.28, 3.33)
eGFR (cut-offs: 60 ml/min/1.73m2)
<60 ml/min/1.73m2 7/ 106 (6.6%) 9/ 78 (11.5%) 0.57 (0.21, 1.53) 0.8568
>=60 ml/min/1.73m2 7/ 124 (5.6%) 13/ 151 (8.6%) 0.63 (0.25, 1.59)
eGFR (cut-offs: 15, 30 and 60 ml/min/1.73m2)
15 - <30 ml/min/1.73m2 0/ 1 (0.0%) 2/ 4 (50.0%) 0.9899
30 - <60 ml/min/1.73m2 7/ 105 (6.7%) 7/ 74 (9.5%) 0.72 (0.25, 2.05)
>=60 ml/min/1.73m2 7/ 124 (5.6%) 13/ 151 (8.6%) 0.63 (0.25, 1.59)
eGFR (cut-offs: 30, 50 and 80 ml/min/1.73m2)
<30 ml/min/1.73m2 0/ 1 (0.0%) 2/ 4 (50.0%) 0.1085
30 - 50 ml/min/1.73m2 6/ 54 (11.1%) 3/ 30 (10.0%) 1.09 (0.27, 4.36)
>50 - 80 ml/min/1.73m2 3/ 128 (2.3%) 14/ 142 (9.9%) 0.22 (0.06, 0.75)
>80 ml/min/1.73m2 5/ 47 (10.6%) 3/ 53 (5.7%) 2.04 (0.49, 8.54)
Fragile subjects
No 3/ 99 (3.0%) 3/ 107 (2.8%) 1.08 (0.22, 5.36) 0.3845
Yes 11/ 131 (8.4%) 19/ 122 (15.6%) 0.51 (0.24, 1.06)
Prior coronary artery disease
No 9/ 141 (6.4%) 14/ 149 (9.4%) 0.66 (0.29, 1.54) 0.7446
Yes 5/ 89 (5.6%) 8/ 80 (10.0%) 0.52 (0.17, 1.58)
Prior MI
No 12/ 211 (5.7%) 20/ 212 (9.4%) 0.59 (0.29, 1.20) 0.7217
Yes 2/ 19 (10.5%) 2/ 17 (11.8%) 0.84 (0.12, 5.96)
Prior MI and age <65 years
No 2/ 15 (13.3%) 2/ 16 (12.5%) 1.41 (0.20, 10.12) 1.0000
Yes 0/ 4 (0.0%) 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) 0.7674
Yes 1/ 10 (10.0%) 1/ 7 (14.3%) 0.65 (0.04, 10.73)
Prior history of limb revascularization
No 7/ 128 (5.5%) 10/ 128 (7.8%) 0.71 (0.27, 1.88) 0.6561
Yes 7/ 102 (6.9%) 12/ 101 (11.9%) 0.52 (0.21, 1.33)
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 13/ 207 (6.3%) 21/ 218 (9.6%) 0.65 (0.33, 1.30) 0.6103
Yes 1/ 23 (4.3%) 1/ 11 (9.1%)
History of heart failure
No 13/ 217 (6.0%) 20/ 219 (9.1%) 0.64 (0.32, 1.29) 0.5804
Yes 1/ 13 (7.7%) 2/ 10 (20.0%) 0.32 (0.03, 3.56)
Diabetes mellitus
No 7/ 124 (5.6%) 14/ 120 (11.7%) 0.48 (0.19, 1.19) 0.3928
Yes 7/ 106 (6.6%) 8/ 109 (7.3%) 0.86 (0.31, 2.38)
Smoking status
NEVER 1/ 40 (2.5%) 3/ 32 (9.4%) 0.25 (0.03, 2.42) 0.2420
FORMER 6/ 126 (4.8%) 14/ 139 (10.1%) 0.45 (0.17, 1.16)
CURRENT 7/ 64 (10.9%) 5/ 58 (8.6%) 1.32 (0.42, 4.14)
Hypertension
No 4/ 42 (9.5%) 2/ 40 (5.0%) 2.36 (0.43, 13.06) 0.1083
Yes 10/ 188 (5.3%) 20/ 189 (10.6%) 0.48 (0.22, 1.02)
Hyperlipidemia
No 9/ 92 (9.8%) 14/ 92 (15.2%) 0.64 (0.28, 1.48) 0.9146
Yes 5/ 138 (3.6%) 8/ 137 (5.8%) 0.59 (0.19, 1.80)
ABI/TBI categories at baseline (Month 1 visit)
ABI <= 0.80 or TBI <= 0.60 1/ 44 (2.3%) 3/ 27 (11.1%) 0.17 (0.02, 1.63) 0.6399
ABI > 0.80 and/or TBI > 0.60 10/ 179 (5.6%) 19/ 201 (9.5%) 0.57 (0.27, 1.23)
TBI and ABI not done 3/ 7 (42.9%) 0/ 1 (0.0%)
Weight group (cut-offs: 70 and 90 kg)
<=70 kg 12/ 196 (6.1%) 20/ 203 (9.9%) 0.61 (0.30, 1.25) 0.9947
>70 - <=90 kg 2/ 31 (6.5%) 2/ 24 (8.3%) 0.61 (0.09, 4.41)
>90 kg 0/ 1 (0.0%) 0/ 1 (0.0%)
Weight group (cut-off 50 kg)
<50 kg 1/ 39 (2.6%) 9/ 51 (17.6%) 0.13 (0.02, 1.01) 0.0733
>=50 kg 13/ 189 (6.9%) 13/ 177 (7.3%) 0.94 (0.43, 2.02)
Weight group (cut-offs: 50, 70 and 90 kg)
<=50 kg 1/ 39 (2.6%) 9/ 52 (17.3%) 0.13 (0.02, 1.02) 0.3520
50 - <=70 kg 11/ 157 (7.0%) 11/ 151 (7.3%) 0.99 (0.43, 2.28)
70 - <=90 kg 2/ 31 (6.5%) 2/ 24 (8.3%) 0.61 (0.09, 4.41)
>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%) 4/ 8 (50.0%) 0.76 (0.09, 6.88) 0.7310
30-<50 mL/min 6/ 71 (8.5%) 6/ 46 (13.0%) 0.56 (0.18, 1.74)
50-80 mL/min 4/ 109 (3.7%) 9/ 116 (7.8%) 0.45 (0.14, 1.47)
>80mL/min 3/ 45 (6.7%) 3/ 58 (5.2%) 1.39 (0.28, 6.90)
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) 0.7295
<15 mL/min 0/ 0 0/ 1 (0.0%)
15-<30 mL/min 1/ 3 (33.3%) 4/ 7 (57.1%) 0.65 (0.07, 5.82)
30-<50 mL/min 6/ 71 (8.5%) 6/ 46 (13.0%) 0.56 (0.18, 1.74)
50-80 mL/min 4/ 109 (3.7%) 9/ 116 (7.8%) 0.45 (0.14, 1.47)
>80 mL/min 3/ 45 (6.7%) 3/ 58 (5.2%) 1.39 (0.28, 6.90)
Clopidogrel use with study ASA after randomization 0.6545
None 5/ 114 (4.4%) 12/ 114 (10.5%) 0.40 (0.14, 1.12)
>0 - <=30 days 7/ 63 (11.1%) 5/ 63 (7.9%) 1.39 (0.44, 4.38)
>30 - <=60 days 1/ 16 (6.3%) 2/ 19 (10.5%) 0.59 (0.05, 6.48)
>60 - <=180 days 0/ 24 (0.0%) 3/ 22 (13.6%)
>180 days 1/ 11 (9.1%) 0/ 8 (0.0%)
Atrial fibrillation disease history 0.8365
No 13/ 224 (5.8%) 21/ 226 (9.3%) 0.61 (0.31, 1.22)
Yes 1/ 6 (16.7%) 1/ 3 (33.3%) 0.41 (0.03, 6.62)
Atrial flutter disease history
No 14/ 230 (6.1%) 22/ 229 (9.6%) 0.62 (0.32, 1.21) N/A
Critical limb ischemia 0.1377
No 13/ 197 (6.6%) 16/ 198 (8.1%) 0.80 (0.38, 1.66)
Yes 1/ 33 (3.0%) 6/ 31 (19.4%) 0.15 (0.02, 1.25)
Critical leg ischemia categories 0.2840
No critical leg ischemia 13/ 197 (6.6%) 16/ 198 (8.1%) 0.80 (0.38, 1.66)
Critical leg ischemia history 0/ 15 (0.0%) 0/ 14 (0.0%)
Critical leg ischemia ongoing 1/ 18 (5.6%) 6/ 17 (35.3%) 0.13 (0.02, 1.11)
Length of target lesion on the index leg 0.2599
SHORT (< 5 CM) 4/ 70 (5.7%) 6/ 56 (10.7%) 0.48 (0.13, 1.69)
INTERMEDIATE (5 CM TO < 15 CM) 5/ 73 (6.8%) 4/ 82 (4.9%) 1.60 (0.43, 5.96)
LONG (>= 15 CM) 5/ 87 (5.7%) 12/ 91 (13.2%) 0.40 (0.14, 1.13)
Time from qualifying revasc. procedure to randomization 0.9825
< Median (Days) 6/ 132 (4.5%) 9/ 120 (7.5%) 0.62 (0.22, 1.75)
>= Median (Days) 8/ 98 (8.2%) 13/ 109 (11.9%) 0.63 (0.26, 1.51)
Statin use during study 0.2011
No 11/ 84 (13.1%) 13/ 84 (15.5%) 0.86 (0.38, 1.91)
Yes 3/ 146 (2.1%) 9/ 145 (6.2%) 0.31 (0.08, 1.15)
PAD symptom status (Rutherford score) (<=2, 3, >=4) 0.7238
<=2 8/ 97 (8.2%) 12/ 107 (11.2%) 0.72 (0.30, 1.77)
3 6/ 106 (5.7%) 4/ 98 (4.1%) 1.32 (0.37, 4.68)
>=4 0/ 27 (0.0%) 6/ 24 (25.0%)
PAD symptom status (Rutherford score) (<=2, 3, 4, >=5) 0.8855
<=2 8/ 97 (8.2%) 12/ 107 (11.2%) 0.72 (0.30, 1.77)
3 6/ 106 (5.7%) 4/ 98 (4.1%) 1.32 (0.37, 4.68)
4 0/ 13 (0.0%) 4/ 11 (36.4%)
>= 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 14.2.5.2/67