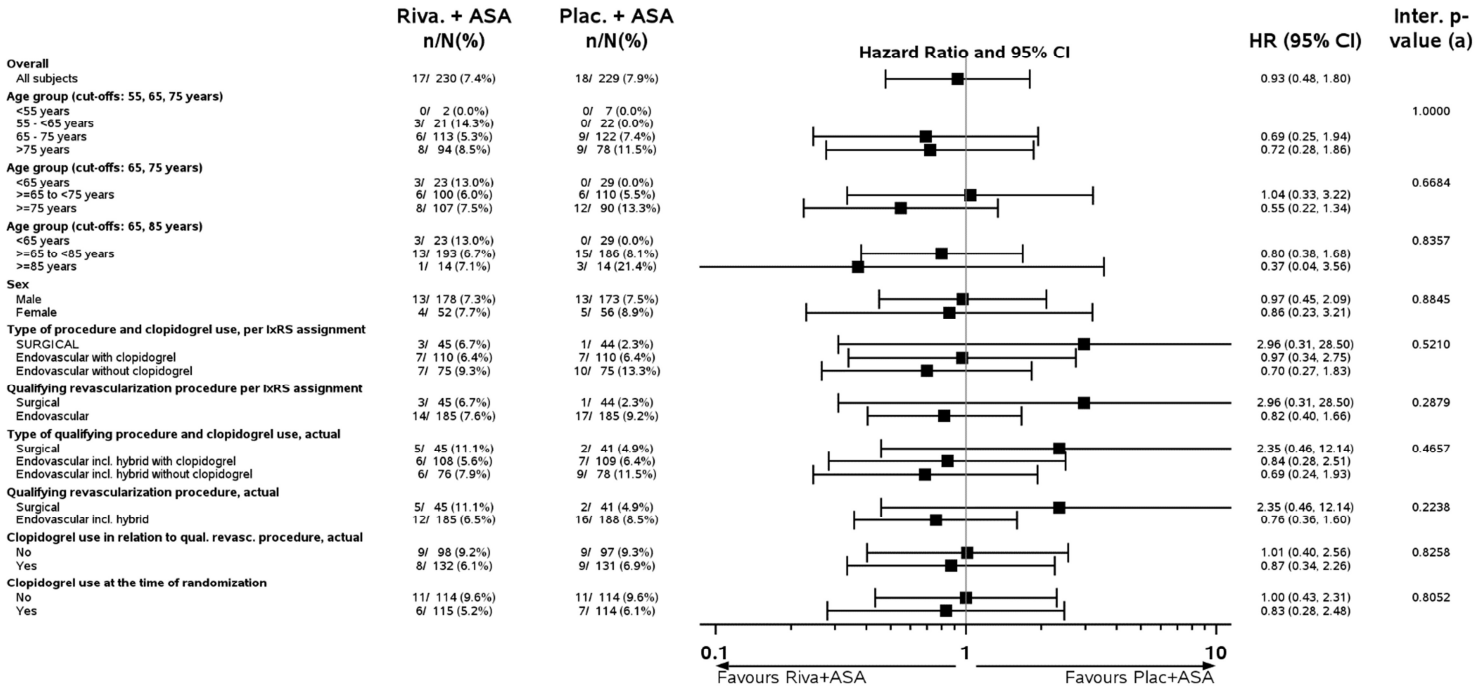
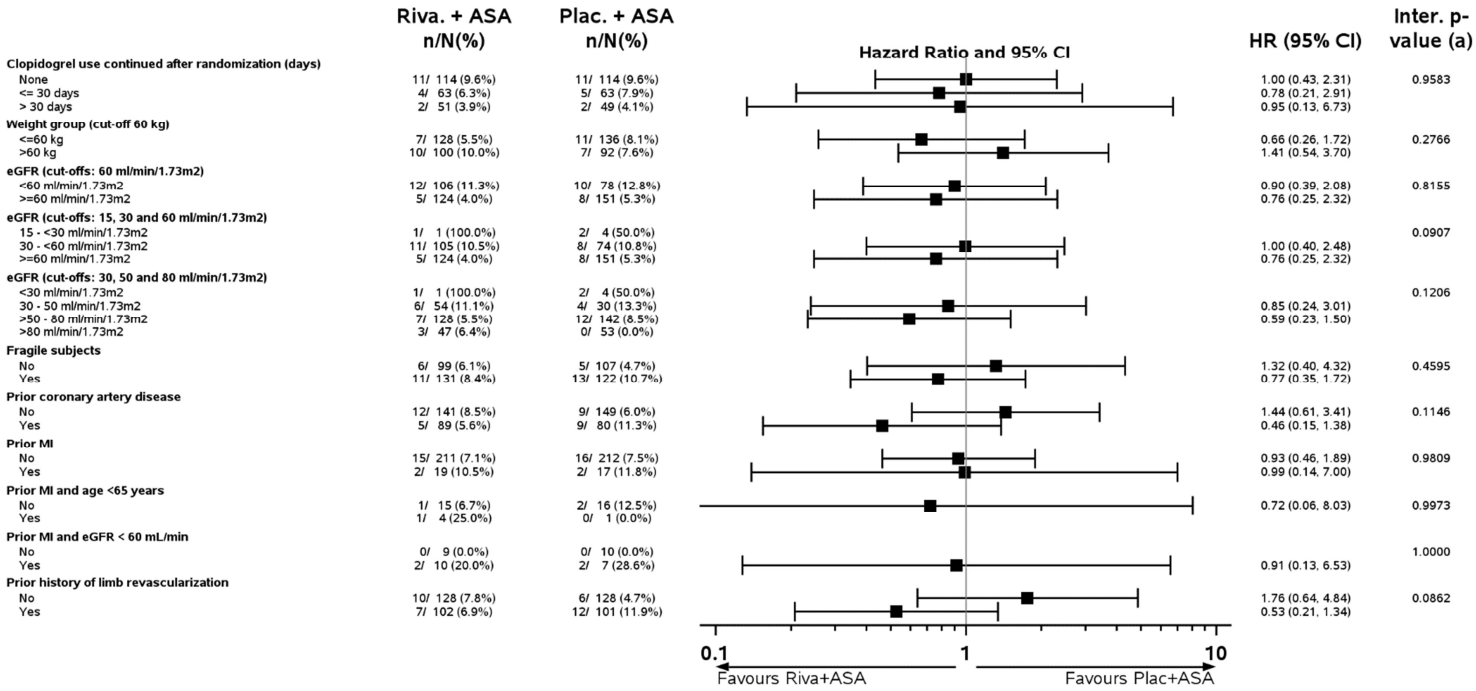
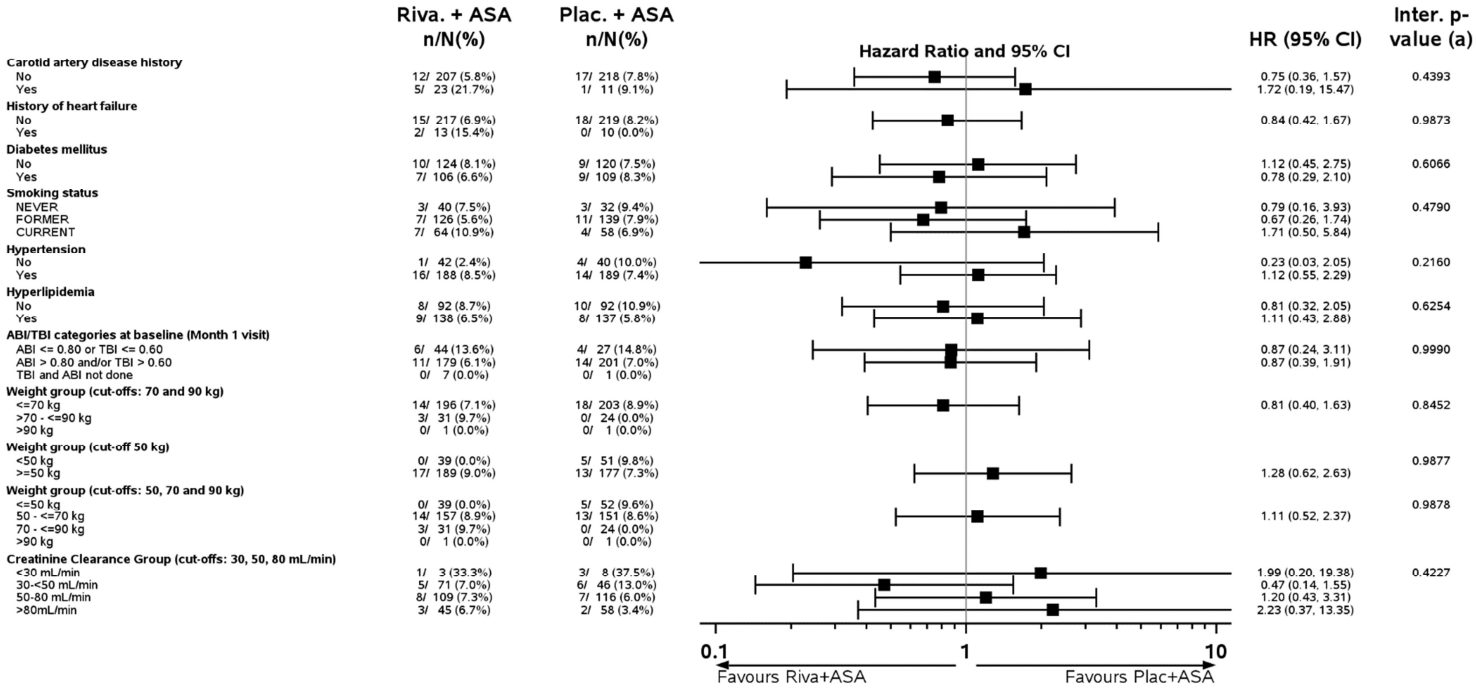
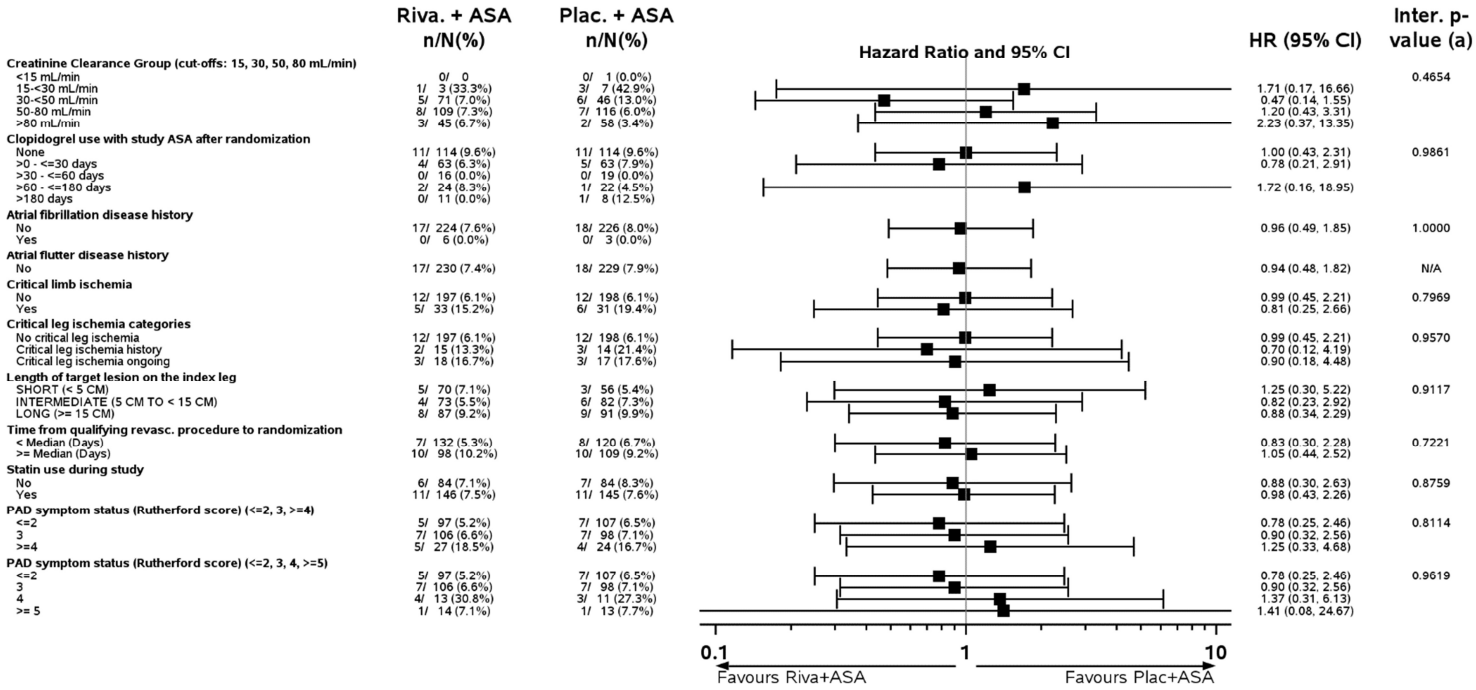
図 2.7.3.7-20 MACE の Forest プロット（試験 17454、日本人集団、ITT、ECOD まで、ICAC 判定）




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 11/ 114 (9.6%) 11/ 114 (9.6%) 1.00 (0.43, 2.31) 0.9583
<= 30 days 4/ 63 (6.3%) 5/ 63 (7.9%) 0.78 (0.21, 2.91)
> 30 days 2/ 51 (3.9%) 2/ 49 (4.1%) 0.95 (0.13, 6.73)
Weight group (cut-off 60 kg)
<=60 kg 7/ 128 (5.5%) 11/ 136 (8.1%) 0.66 (0.26, 1.72) 0.2766
>60 kg 10/ 100 (10.0%) 7/ 92 (7.6%) 1.41 (0.54, 3.70)
eGFR (cut-offs: 60 ml/min/1.73m2)
<60 ml/min/1.73m2 12/ 106 (11.3%) 10/ 78 (12.8%) 0.90 (0.39, 2.08) 0.8155
>=60 ml/min/1.73m2 5/ 124 (4.0%) 8/ 151 (5.3%) 0.76 (0.25, 2.32)
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%) 0.0907
30 - <60 ml/min/1.73m2 11/ 105 (10.5%) 8/ 74 (10.8%) 1.00 (0.40, 2.48)
>=60 ml/min/1.73m2 5/ 124 (4.0%) 8/ 151 (5.3%) 0.76 (0.25, 2.32)
eGFR (cut-offs: 30, 50 and 80 ml/min/1.73m2)
<30 ml/min/1.73m2 1/ 1 (100.0%) 2/ 4 (50.0%) 0.1206
30 - 50 ml/min/1.73m2 6/ 54 (11.1%) 4/ 30 (13.3%) 0.85 (0.24, 3.01)
>50 - 80 ml/min/1.73m2 7/ 128 (5.5%) 12/ 142 (8.5%) 0.59 (0.23, 1.50)
>80 ml/min/1.73m2 3/ 47 (6.4%) 0/ 53 (0.0%)
Fragile subjects
No 6/ 99 (6.1%) 5/ 107 (4.7%) 1.32 (0.40, 4.32) 0.4595
Yes 11/ 131 (8.4%) 13/ 122 (10.7%) 0.77 (0.35, 1.72)
Prior coronary artery disease
No 12/ 141 (8.5%) 9/ 149 (6.0%) 1.44 (0.61, 3.41) 0.1146
Yes 5/ 89 (5.6%) 9/ 80 (11.3%) 0.46 (0.15, 1.38)
Prior MI
No 15/ 211 (7.1%) 16/ 212 (7.5%) 0.93 (0.46, 1.89) 0.9809
Yes 2/ 19 (10.5%) 2/ 17 (11.8%) 0.99 (0.14, 7.00)
Prior MI and age <65 years
No 1/ 15 (6.7%) 2/ 16 (12.5%) 0.72 (0.06, 8.03) 0.9973
Yes 1/ 4 (25.0%) 0/ 1 (0.0%)
Prior MI and eGFR < 60 mL/min
No 0/ 9 (0.0%) 0/ 10 (0.0%) 1.0000
Yes 2/ 10 (20.0%) 2/ 7 (28.6%) 0.91 (0.13, 6.53)
Prior history of limb revascularization
No 10/ 128 (7.8%) 6/ 128 (4.7%) 1.76 (0.64, 4.84) 0.0862
Yes 7/ 102 (6.9%) 12/ 101 (11.9%) 0.53 (0.21, 1.34)
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 12/ 207 (5.8%) 17/ 218 (7.8%) 0.75 (0.36, 1.57) 0.4393
Yes 5/ 23 (21.7%) 1/ 11 (9.1%) 1.72 (0.19, 15.47)
History of heart failure
No 15/ 217 (6.9%) 18/ 219 (8.2%) 0.84 (0.42, 1.67) 0.9873
Yes 2/ 13 (15.4%) 0/ 10 (0.0%)
Diabetes mellitus
No 10/ 124 (8.1%) 9/ 120 (7.5%) 1.12 (0.45, 2.75) 0.6066
Yes 7/ 106 (6.6%) 9/ 109 (8.3%) 0.78 (0.29, 2.10)
Smoking status
NEVER 3/ 40 (7.5%) 3/ 32 (9.4%) 0.79 (0.16, 3.93) 0.4790
FORMER 7/ 126 (5.6%) 11/ 139 (7.9%) 0.67 (0.26, 1.74)
CURRENT 7/ 64 (10.9%) 4/ 58 (6.9%) 1.71 (0.50, 5.84)
Hypertension
No 1/ 42 (2.4%) 4/ 40 (10.0%) 0.23 (0.03, 2.05) 0.2160
Yes 16/ 188 (8.5%) 14/ 189 (7.4%) 1.12 (0.55, 2.29)
Hyperlipidemia
No 8/ 92 (8.7%) 10/ 92 (10.9%) 0.81 (0.32, 2.05) 0.6254
Yes 9/ 138 (6.5%) 8/ 137 (5.8%) 1.11 (0.43, 2.88)
ABI/TBI categories at baseline (Month 1 visit)
ABI <= 0.80 or TBI <= 0.60 6/ 44 (13.6%) 4/ 27 (14.8%) 0.87 (0.24, 3.11) 0.9990
ABI > 0.80 and/or TBI > 0.60 11/ 179 (6.1%) 14/ 201 (7.0%) 0.87 (0.39, 1.91)
TBI and ABI not done 0/ 7 (0.0%) 0/ 1 (0.0%)
Weight group (cut-offs: 70 and 90 kg)
<=70 kg 14/ 196 (7.1%) 18/ 203 (8.9%) 0.81 (0.40, 1.63) 0.8452
>70 - <=90 kg 3/ 31 (9.7%) 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%) 5/ 51 (9.8%) 0.9877
>=50 kg 17/ 189 (9.0%) 13/ 177 (7.3%) 1.28 (0.62, 2.63)
Weight group (cut-offs: 50, 70 and 90 kg)
<=50 kg 0/ 39 (0.0%) 5/ 52 (9.6%) 0.9878
50 - <=70 kg 14/ 157 (8.9%) 13/ 151 (8.6%) 1.11 (0.52, 2.37)
70 - <=90 kg 3/ 31 (9.7%) 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 1/ 3 (33.3%) 3/ 8 (37.5%) 1.99 (0.20, 19.38) 0.4227
30-<50 mL/min 5/ 71 (7.0%) 6/ 46 (13.0%) 0.47 (0.14, 1.55)
50-80 mL/min 8/ 109 (7.3%) 7/ 116 (6.0%) 1.20 (0.43, 3.31)
>80mL/min 3/ 45 (6.7%) 2/ 58 (3.4%) 2.23 (0.37, 13.35)
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) 0.4654
<15 mL/min 0/ 0 0/ 1 (0.0%)
15-<30 mL/min 1/ 3 (33.3%) 3/ 7 (42.9%) 1.71 (0.17, 16.66)
30-<50 mL/min 5/ 71 (7.0%) 6/ 46 (13.0%) 0.47 (0.14, 1.55)
50-80 mL/min 8/ 109 (7.3%) 7/ 116 (6.0%) 1.20 (0.43, 3.31)
>80 mL/min 3/ 45 (6.7%) 2/ 58 (3.4%) 2.23 (0.37, 13.35)
Clopidogrel use with study ASA after randomization 0.9861
None 11/ 114 (9.6%) 11/ 114 (9.6%) 1.00 (0.43, 2.31)
>0 - <=30 days 4/ 63 (6.3%) 5/ 63 (7.9%) 0.78 (0.21, 2.91)
>30 - <=60 days 0/ 16 (0.0%) 0/ 19 (0.0%)
>60 - <=180 days 2/ 24 (8.3%) 1/ 22 (4.5%) 1.72 (0.16, 18.95)
>180 days 0/ 11 (0.0%) 1/ 8 (12.5%)
Atrial fibrillation disease history 1.0000
No 17/ 224 (7.6%) 18/ 226 (8.0%) 0.96 (0.49, 1.85)
Yes 0/ 6 (0.0%) 0/ 3 (0.0%)
Atrial flutter disease history N/A
No 17/ 230 (7.4%) 18/ 229 (7.9%) 0.94 (0.48, 1.82)
Critical limb ischemia 0.7969
No 12/ 197 (6.1%) 12/ 198 (6.1%) 0.99 (0.45, 2.21)
Yes 5/ 33 (15.2%) 6/ 31 (19.4%) 0.81 (0.25, 2.66)
Critical leg ischemia categories 0.9570
No critical leg ischemia 12/ 197 (6.1%) 12/ 198 (6.1%) 0.99 (0.45, 2.21)
Critical leg ischemia history 2/ 15 (13.3%) 3/ 14 (21.4%) 0.70 (0.12, 4.19)
Critical leg ischemia ongoing 3/ 18 (16.7%) 3/ 17 (17.6%) 0.90 (0.18, 4.48)
Length of target lesion on the index leg 0.9117
SHORT (< 5 CM) 5/ 70 (7.1%) 3/ 56 (5.4%) 1.25 (0.30, 5.22)
INTERMEDIATE (5 CM TO < 15 CM) 4/ 73 (5.5%) 6/ 82 (7.3%) 0.82 (0.23, 2.92)
LONG (>= 15 CM) 8/ 87 (9.2%) 9/ 91 (9.9%) 0.88 (0.34, 2.29)
Time from qualifying revasc. procedure to randomization 0.7221
< Median (Days) 7/ 132 (5.3%) 8/ 120 (6.7%) 0.83 (0.30, 2.28)
>= Median (Days) 10/ 98 (10.2%) 10/ 109 (9.2%) 1.05 (0.44, 2.52)
Statin use during study 0.8759
No 6/ 84 (7.1%) 7/ 84 (8.3%) 0.88 (0.30, 2.63)
Yes 11/ 146 (7.5%) 11/ 145 (7.6%) 0.98 (0.43, 2.26)
PAD symptom status (Rutherford score) (<=2, 3, >=4) 0.8114
<=2 5/ 97 (5.2%) 7/ 107 (6.5%) 0.78 (0.25, 2.46)
3 7/ 106 (6.6%) 7/ 98 (7.1%) 0.90 (0.32, 2.56)
>=4 5/ 27 (18.5%) 4/ 24 (16.7%) 1.25 (0.33, 4.68)
PAD symptom status (Rutherford score) (<=2, 3, 4, >=5) 0.9619
<=2 5/ 97 (5.2%) 7/ 107 (6.5%) 0.78 (0.25, 2.46)
3 7/ 106 (6.6%) 7/ 98 (7.1%) 0.90 (0.32, 2.56)
4 4/ 13 (30.8%) 3/ 11 (27.3%) 1.37 (0.31, 6.13)
>= 5 1/ 14 (7.1%) 1/ 13 (7.7%) 1.41 (0.08, 24.67)
0.1
1
10
Favours Riva+ASA
Favours Plac+ASA

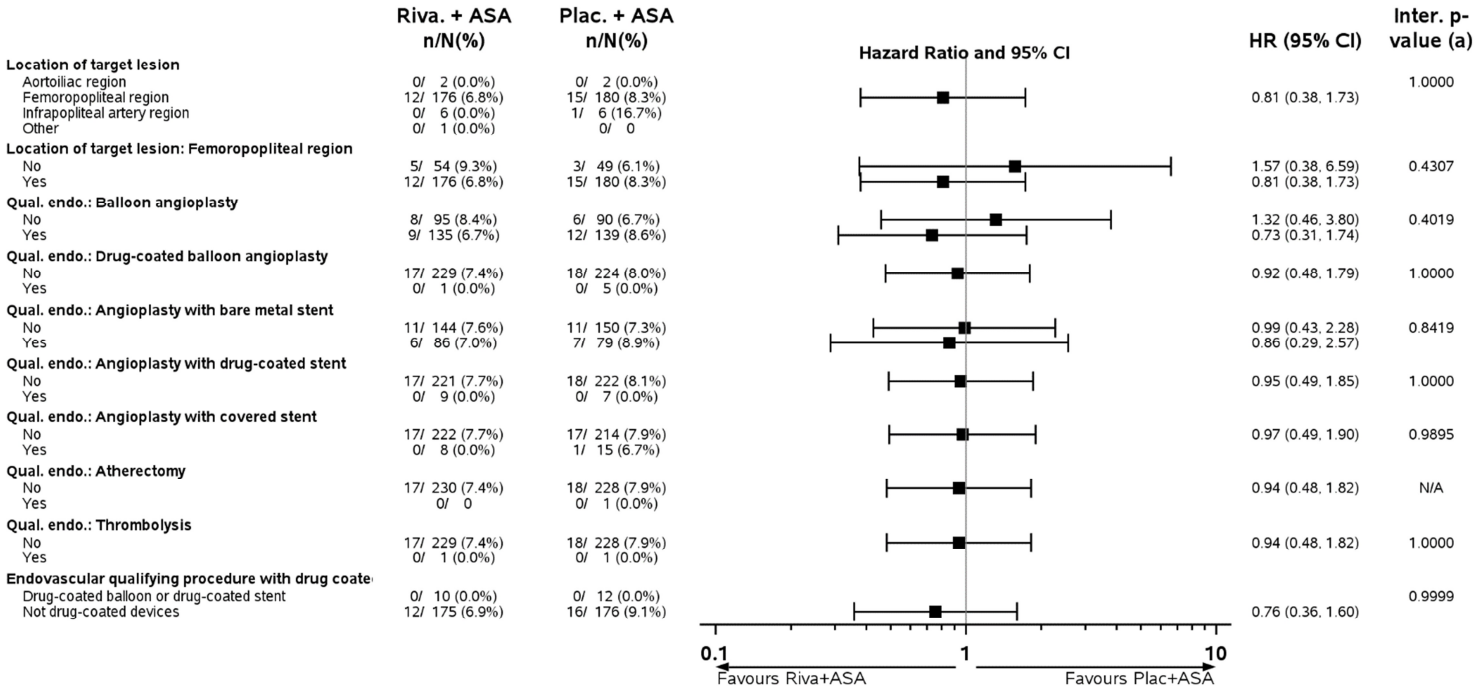
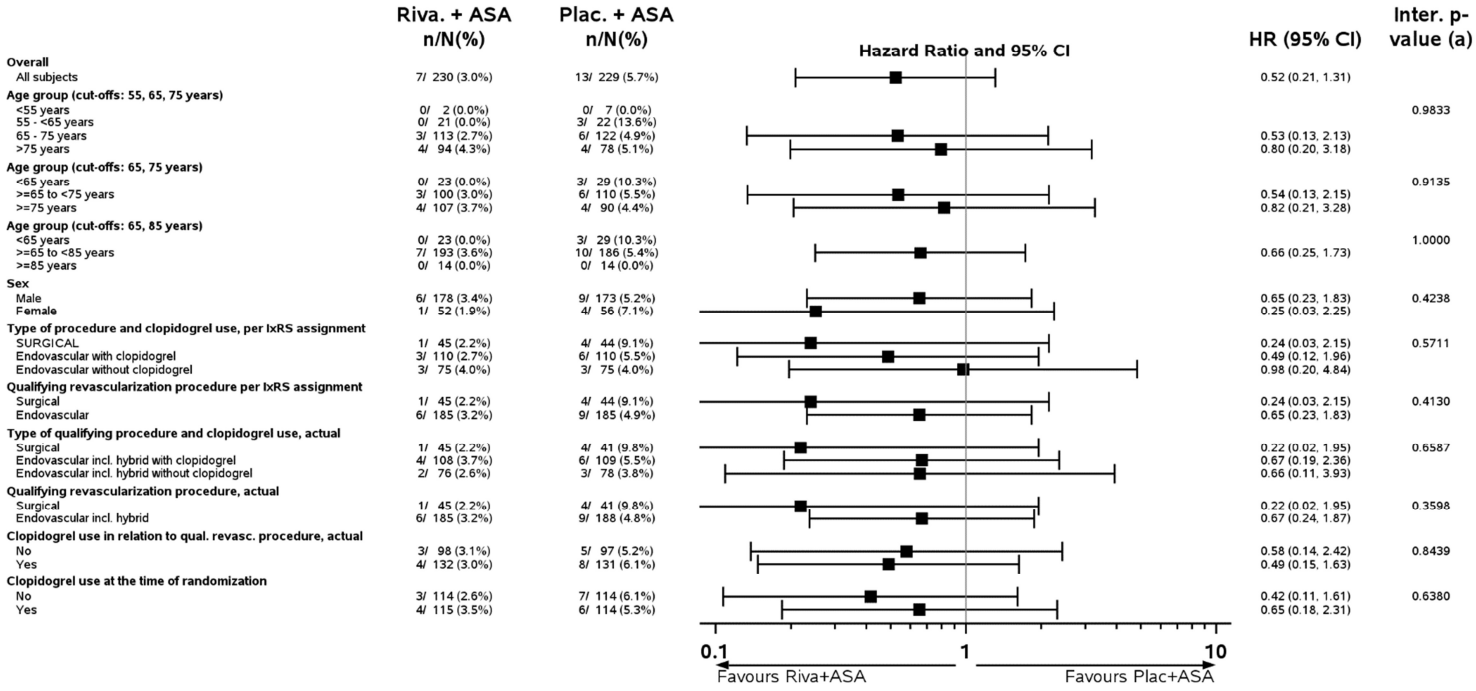
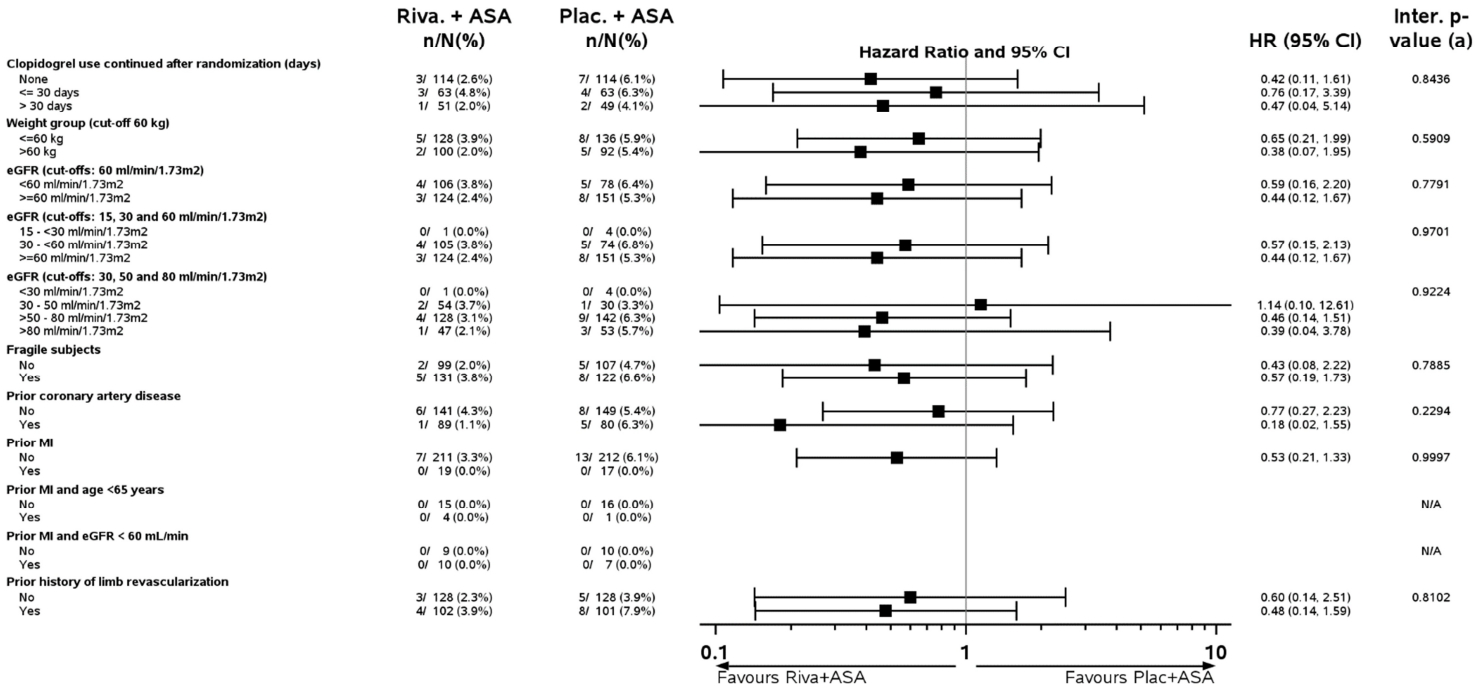


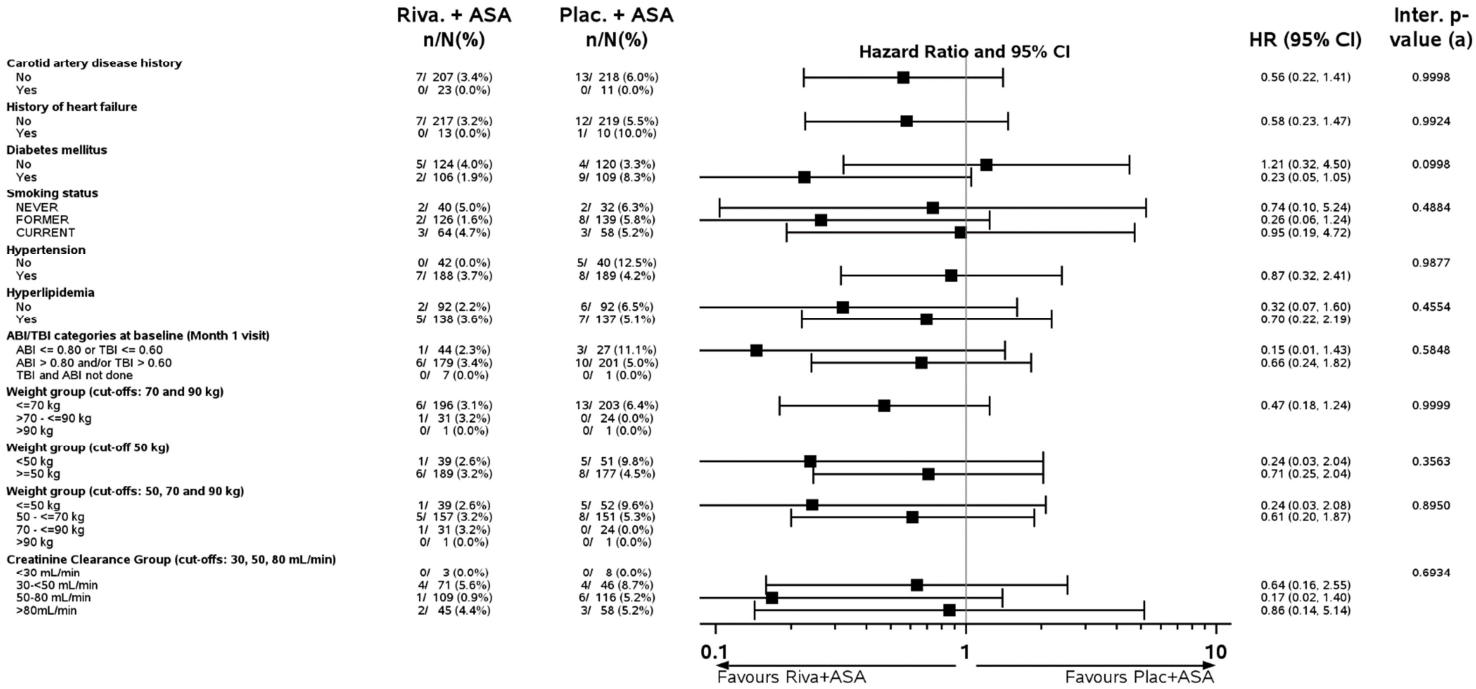
Figure displays outcome events meeting the definition as adjudicated by Independent Clinical Adjudication Committee (ICAC). Subgroup variables from Atrial fibrillation disease history and below are added post-hoc.
The ITT analysis set includes all randomized subjects. The ITT data scope includes outcome events observed from randomization date until efficacy cut-off date.
Subjects will be considered fragile if age >75 years or weight <=50 kg or baseline eGFR <50 mL/min/1.73m2. Efficacy cut-off date = 08SEP2019
CV death = Cardiovascular death and unknown death, MACE = Major adverse cardiac event incl. myocardial infarction, ischemic stroke and CV death.
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.

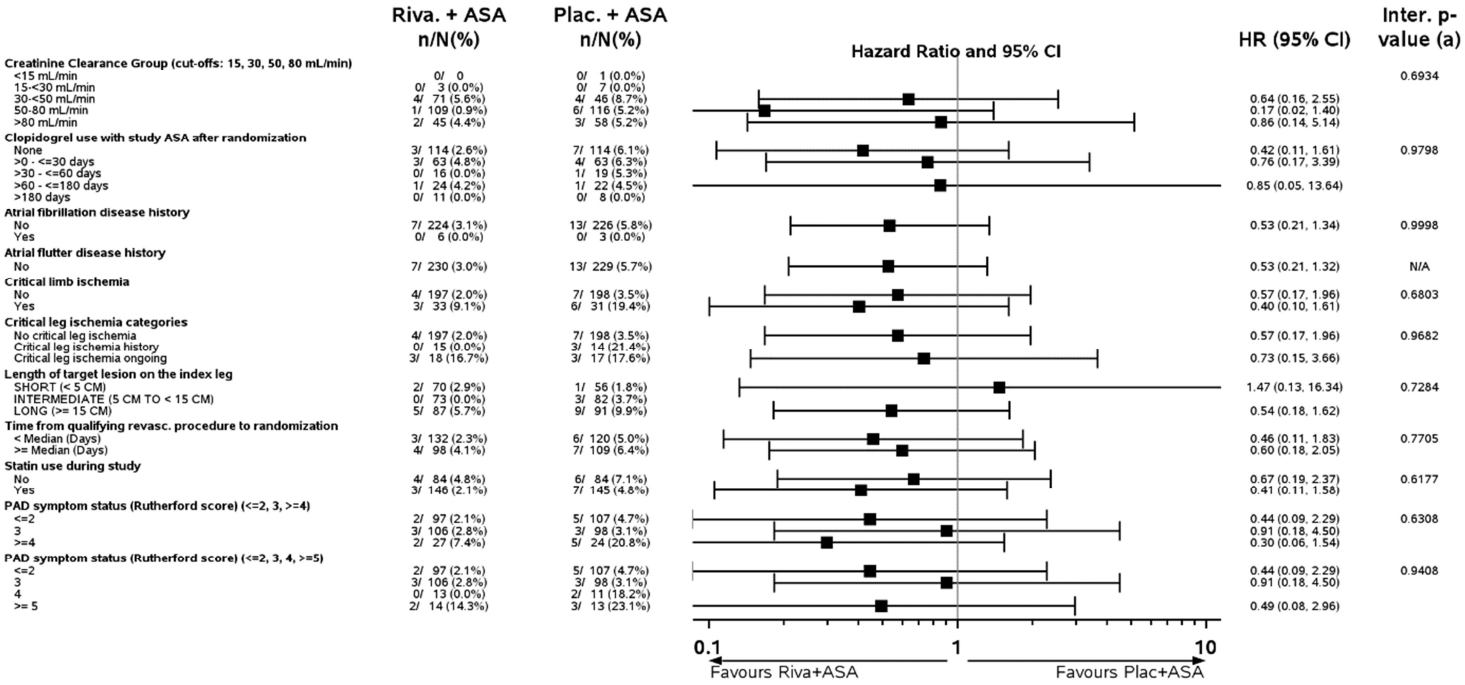
Source: 5.3.5.1.2 17454_J_analysis/Figure 14.2.5.1/13

図 2.7.3.7-21 MALE 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 3/ 114 (2.6%) 7/ 114 (6.1%) 0.42 (0.11, 1.61) 0.8436
<= 30 days 3/ 63 (4.8%) 4/ 63 (6.3%) 0.76 (0.17, 3.39)
> 30 days 1/ 51 (2.0%) 2/ 49 (4.1%) 0.47 (0.04, 5.14)
Weight group (cut-off 60 kg)
<=60 kg 5/ 128 (3.9%) 8/ 136 (5.9%) 0.65 (0.21, 1.99) 0.5909
>60 kg 2/ 100 (2.0%) 5/ 92 (5.4%) 0.38 (0.07, 1.95)
eGFR (cut-offs: 60 ml/min/1.73m2)
<60 ml/min/1.73m2 4/ 106 (3.8%) 5/ 78 (6.4%) 0.59 (0.16, 2.20) 0.7791
>=60 ml/min/1.73m2 3/ 124 (2.4%) 8/ 151 (5.3%) 0.44 (0.12, 1.67)
eGFR (cut-offs: 15, 30 and 60 ml/min/1.73m2)
15 - <30 ml/min/1.73m2 0/ 1 (0.0%) 0/ 4 (0.0%) 0.9701
30 - <60 ml/min/1.73m2 4/ 105 (3.8%) 5/ 74 (6.8%) 0.57 (0.15, 2.13)
>=60 ml/min/1.73m2 3/ 124 (2.4%) 8/ 151 (5.3%) 0.44 (0.12, 1.67)
eGFR (cut-offs: 30, 50 and 80 ml/min/1.73m2)
<30 ml/min/1.73m2 0/ 1 (0.0%) 0/ 4 (0.0%) 0.9224
30 - 50 ml/min/1.73m2 2/ 54 (3.7%) 1/ 30 (3.3%) 1.14 (0.10, 12.61)
>50 - 80 ml/min/1.73m2 4/ 128 (3.1%) 9/ 142 (6.3%) 0.46 (0.14, 1.51)
>80 ml/min/1.73m2 1/ 47 (2.1%) 3/ 53 (5.7%) 0.39 (0.04, 3.78)
Fragile subjects
No 2/ 99 (2.0%) 5/ 107 (4.7%) 0.43 (0.08, 2.22) 0.7885
Yes 5/ 131 (3.8%) 8/ 122 (6.6%) 0.57 (0.19, 1.73)
Prior coronary artery disease
No 6/ 141 (4.3%) 8/ 149 (5.4%) 0.77 (0.27, 2.23) 0.2294
Yes 1/ 89 (1.1%) 5/ 80 (6.3%) 0.18 (0.02, 1.55)
Prior MI
No 7/ 211 (3.3%) 13/ 212 (6.1%) 0.53 (0.21, 1.33) 0.9997
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 3/ 128 (2.3%) 5/ 128 (3.9%) 0.60 (0.14, 2.51) 0.8102
Yes 4/ 102 (3.9%) 8/ 101 (7.9%) 0.48 (0.14, 1.59)
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 7/ 207 (3.4%) 13/ 218 (6.0%) 0.56 (0.22, 1.41) 0.9998
Yes 0/ 23 (0.0%) 0/ 11 (0.0%)
History of heart failure
No 7/ 217 (3.2%) 12/ 219 (5.5%) 0.58 (0.23, 1.47) 0.9924
Yes 0/ 13 (0.0%) 1/ 10 (10.0%)
Diabetes mellitus
No 5/ 124 (4.0%) 4/ 120 (3.3%) 1.21 (0.32, 4.50) 0.0998
Yes 2/ 106 (1.9%) 9/ 109 (8.3%) 0.23 (0.05, 1.05)
Smoking status
NEVER 2/ 40 (5.0%) 2/ 32 (6.3%) 0.74 (0.10, 5.24) 0.4884
FORMER 2/ 126 (1.6%) 8/ 139 (5.8%) 0.26 (0.06, 1.24)
CURRENT 3/ 64 (4.7%) 3/ 58 (5.2%) 0.95 (0.19, 4.72)
Hypertension
No 0/ 42 (0.0%) 5/ 40 (12.5%) 0.9877
Yes 7/ 188 (3.7%) 8/ 189 (4.2%) 0.87 (0.32, 2.41)
Hyperlipidemia
No 2/ 92 (2.2%) 6/ 92 (6.5%) 0.32 (0.07, 1.60) 0.4554
Yes 5/ 138 (3.6%) 7/ 137 (5.1%) 0.70 (0.22, 2.19)
ABI/TBI categories at baseline (Month 1 visit)
ABI <= 0.80 or TBI <= 0.60 1/ 44 (2.3%) 3/ 27 (11.1%) 0.15 (0.01, 1.43) 0.5848
ABI > 0.80 and/or TBI > 0.60 6/ 179 (3.4%) 10/ 201 (5.0%) 0.66 (0.24, 1.82)
TBI and ABI not done 0/ 7 (0.0%) 0/ 1 (0.0%)
Weight group (cut-offs: 70 and 90 kg)
<=70 kg 6/ 196 (3.1%) 13/ 203 (6.4%) 0.47 (0.18, 1.24) 0.9999
>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 1/ 39 (2.6%) 5/ 51 (9.8%) 0.24 (0.03, 2.04) 0.3563
>=50 kg 6/ 189 (3.2%) 8/ 177 (4.5%) 0.71 (0.25, 2.04)
Weight group (cut-offs: 50, 70 and 90 kg)
<=50 kg 1/ 39 (2.6%) 5/ 52 (9.6%) 0.24 (0.03, 2.08) 0.8950
50 - <=70 kg 5/ 157 (3.2%) 8/ 151 (5.3%) 0.61 (0.20, 1.87)
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%) 0/ 8 (0.0%) 0.6934
30-<50 mL/min 4/ 71 (5.6%) 4/ 46 (8.7%) 0.64 (0.16, 2.55)
50-80 mL/min 1/ 109 (0.9%) 6/ 116 (5.2%) 0.17 (0.02, 1.40)
>80mL/min 2/ 45 (4.4%) 3/ 58 (5.2%) 0.86 (0.14, 5.14)
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) 0.6934
<15 mL/min 0/ 0 0/ 1 (0.0%)
15-<30 mL/min 0/ 3 (0.0%) 0/ 7 (0.0%)
30-<50 mL/min 4/ 71 (5.6%) 4/ 46 (8.7%) 0.64 (0.16, 2.55)
50-80 mL/min 1/ 109 (0.9%) 6/ 116 (5.2%) 0.17 (0.02, 1.40)
>80 mL/min 2/ 45 (4.4%) 3/ 58 (5.2%) 0.86 (0.14, 5.14)
Clopidogrel use with study ASA after randomization 0.9798
None 3/ 114 (2.6%) 7/ 114 (6.1%) 0.42 (0.11, 1.61)
>0 - <=30 days 3/ 63 (4.8%) 4/ 63 (6.3%) 0.76 (0.17, 3.39)
>30 - <=60 days 0/ 16 (0.0%) 1/ 19 (5.3%)
>60 - <=180 days 1/ 24 (4.2%) 1/ 22 (4.5%) 0.85 (0.05, 13.64)
>180 days 0/ 11 (0.0%) 0/ 8 (0.0%)
Atrial fibrillation disease history 0.9998
No 7/ 224 (3.1%) 13/ 226 (5.8%) 0.53 (0.21, 1.34)
Yes 0/ 6 (0.0%) 0/ 3 (0.0%)
Atrial flutter disease history N/A
No 7/ 230 (3.0%) 13/ 229 (5.7%) 0.53 (0.21, 1.32)
Critical limb ischemia 0.6803
No 4/ 197 (2.0%) 7/ 198 (3.5%) 0.57 (0.17, 1.96)
Yes 3/ 33 (9.1%) 6/ 31 (19.4%) 0.40 (0.10, 1.61)
Critical leg ischemia categories 0.9682
No critical leg ischemia 4/ 197 (2.0%) 7/ 198 (3.5%) 0.57 (0.17, 1.96)
Critical leg ischemia history 0/ 15 (0.0%) 3/ 14 (21.4%)
Critical leg ischemia ongoing 3/ 18 (16.7%) 3/ 17 (17.6%) 0.73 (0.15, 3.66)
Length of target lesion on the index leg 0.7284
SHORT (< 5 CM) 2/ 70 (2.9%) 1/ 56 (1.8%) 1.47 (0.13, 16.34)
INTERMEDIATE (5 CM TO < 15 CM) 0/ 73 (0.0%) 3/ 82 (3.7%)
LONG (>= 15 CM) 5/ 87 (5.7%) 9/ 91 (9.9%) 0.54 (0.18, 1.62)
Time from qualifying revasc. procedure to randomization 0.7705
< Median (Days) 3/ 132 (2.3%) 6/ 120 (5.0%) 0.46 (0.11, 1.83)
>= Median (Days) 4/ 98 (4.1%) 7/ 109 (6.4%) 0.60 (0.18, 2.05)
Statin use during study 0.6177
No 4/ 84 (4.8%) 6/ 84 (7.1%) 0.67 (0.19, 2.37)
Yes 3/ 146 (2.1%) 7/ 145 (4.8%) 0.41 (0.11, 1.58)
PAD symptom status (Rutherford score) (<=2, 3, >=4) 0.6308
<=2 2/ 97 (2.1%) 5/ 107 (4.7%) 0.44 (0.09, 2.29)
3 3/ 106 (2.8%) 3/ 98 (3.1%) 0.91 (0.18, 4.50)
>=4 2/ 27 (7.4%) 5/ 24 (20.8%) 0.30 (0.06, 1.54)
PAD symptom status (Rutherford score) (<=2, 3, 4, >=5) 0.9408
<=2 2/ 97 (2.1%) 5/ 107 (4.7%) 0.44 (0.09, 2.29)
3 3/ 106 (2.8%) 3/ 98 (3.1%) 0.91 (0.18, 4.50)
4 0/ 13 (0.0%) 2/ 11 (18.2%)
>= 5 2/ 14 (14.3%) 3/ 13 (23.1%) 0.49 (0.08, 2.96)
0.1
1
10
Favours Riva+ASA
Favours Plac+ASA

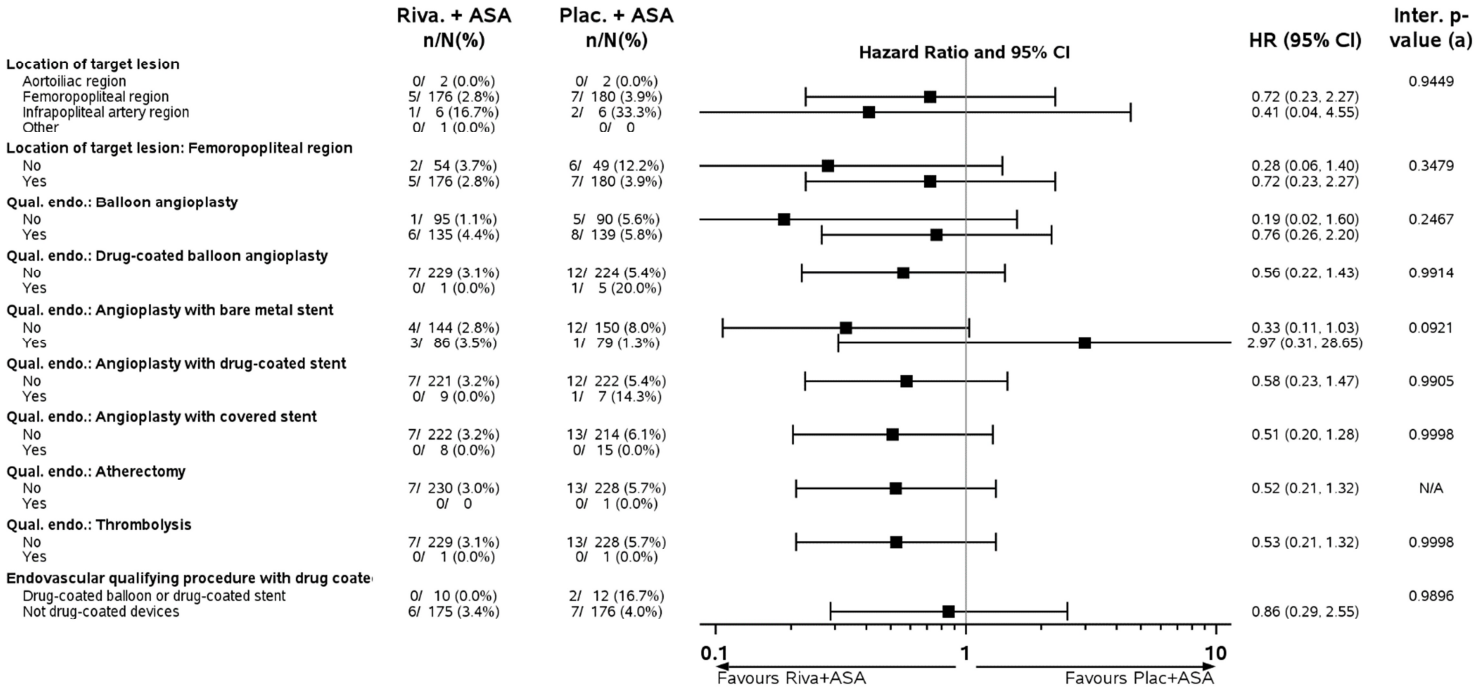


Figure displays outcome events meeting the definition as adjudicated by Independent Clinical Adjudication Committee (ICAC). Subgroup variables from Atrial fibrillation disease history and below are added post-hoc.
The ITT analysis set includes all randomized subjects. The ITT data scope includes outcome events observed from randomization date until efficacy cut-off date.
Subjects will be considered fragile if age >75 years or weight <=50 kg or baseline eGFR <50 mL/min/1.73m2. Efficacy cut-off date = 08SEP2019
MALE = Major adverse limb event including acute limb ischemia and major amputation of vascular etiology.
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 14.2.5.1/49