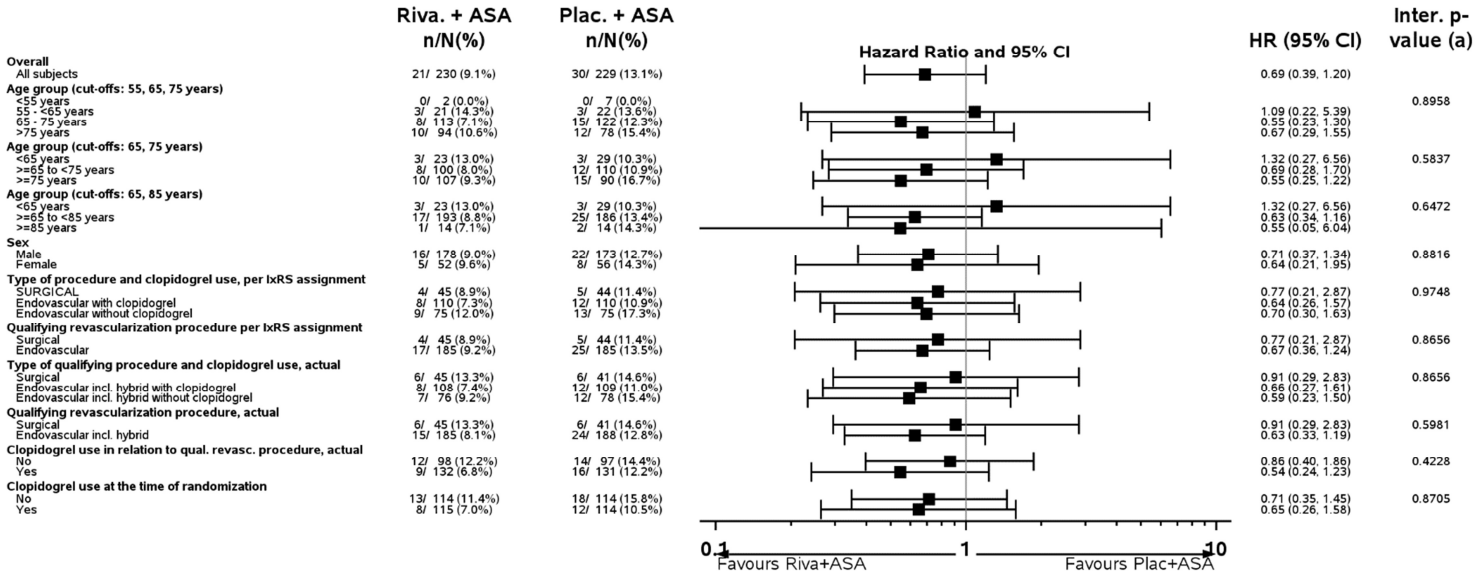
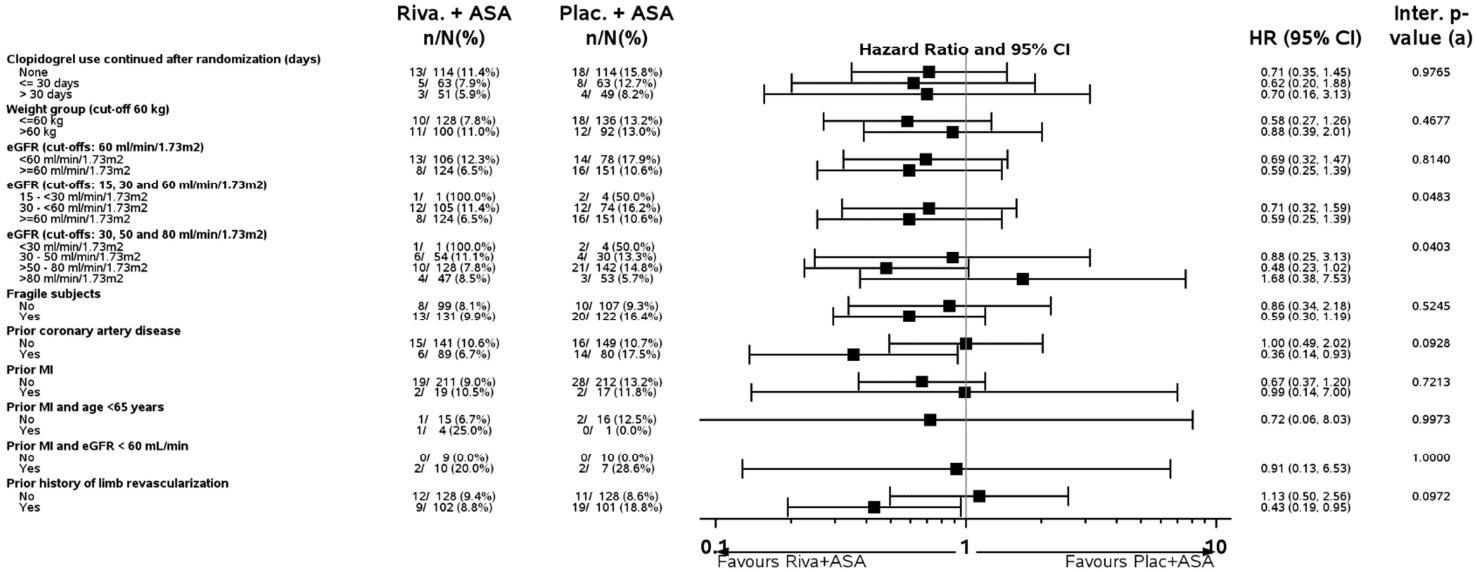
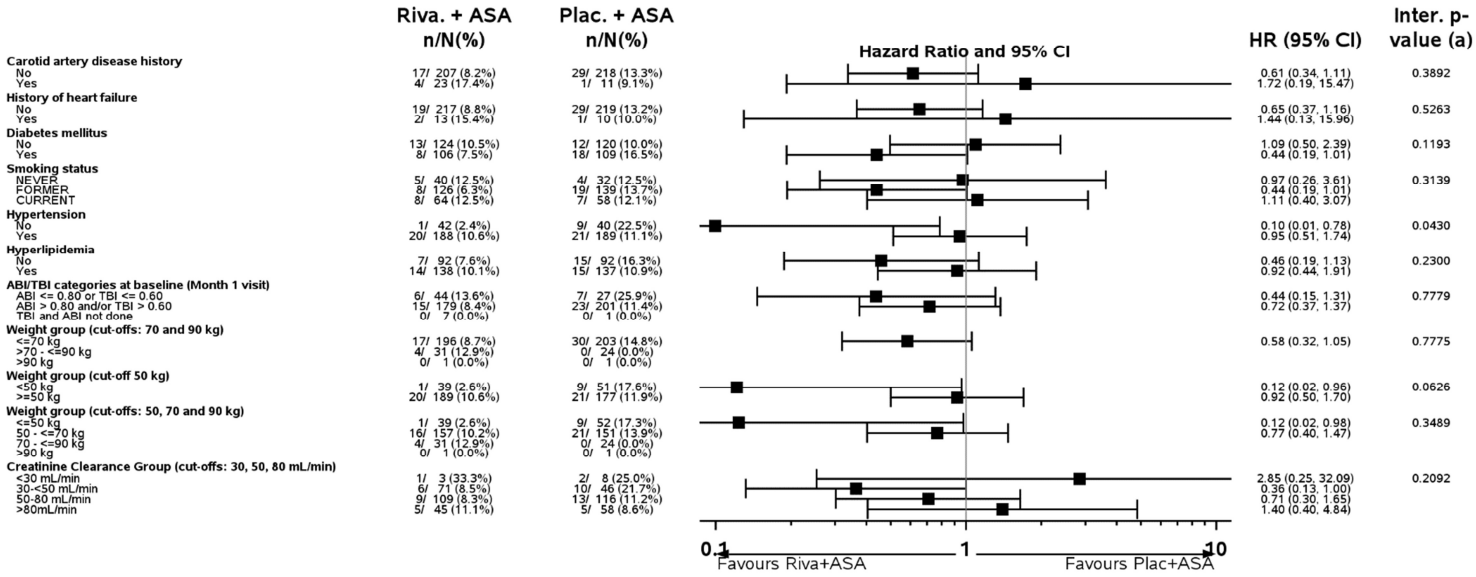
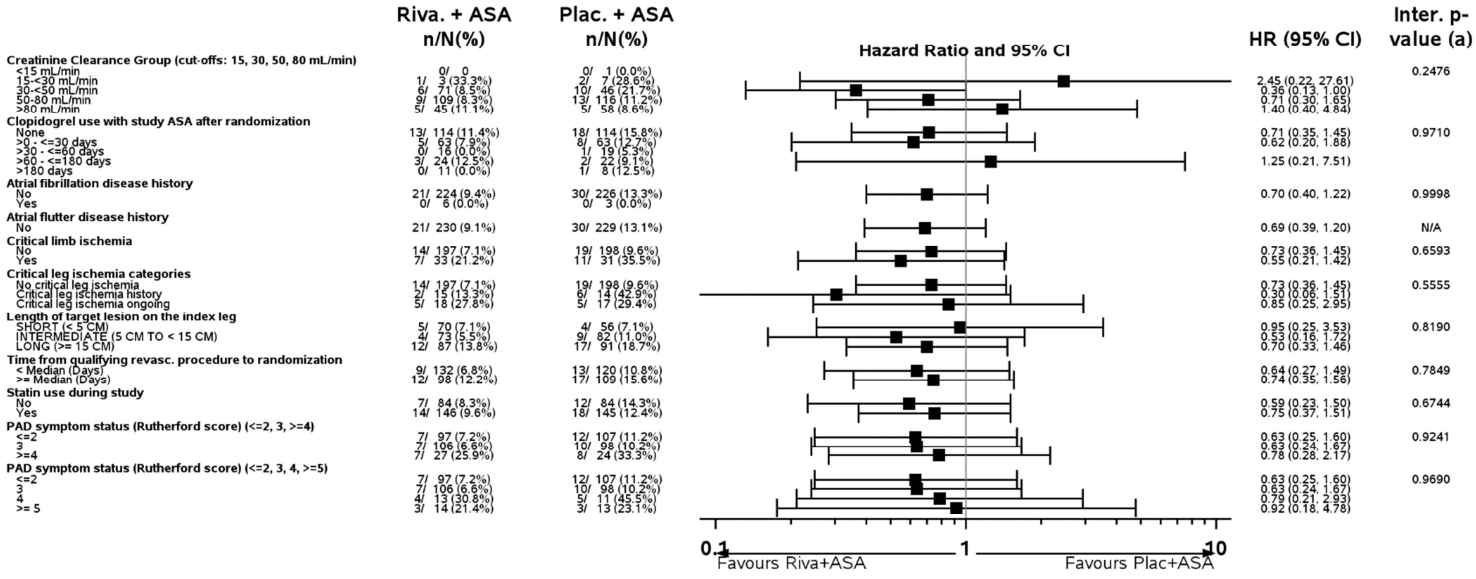
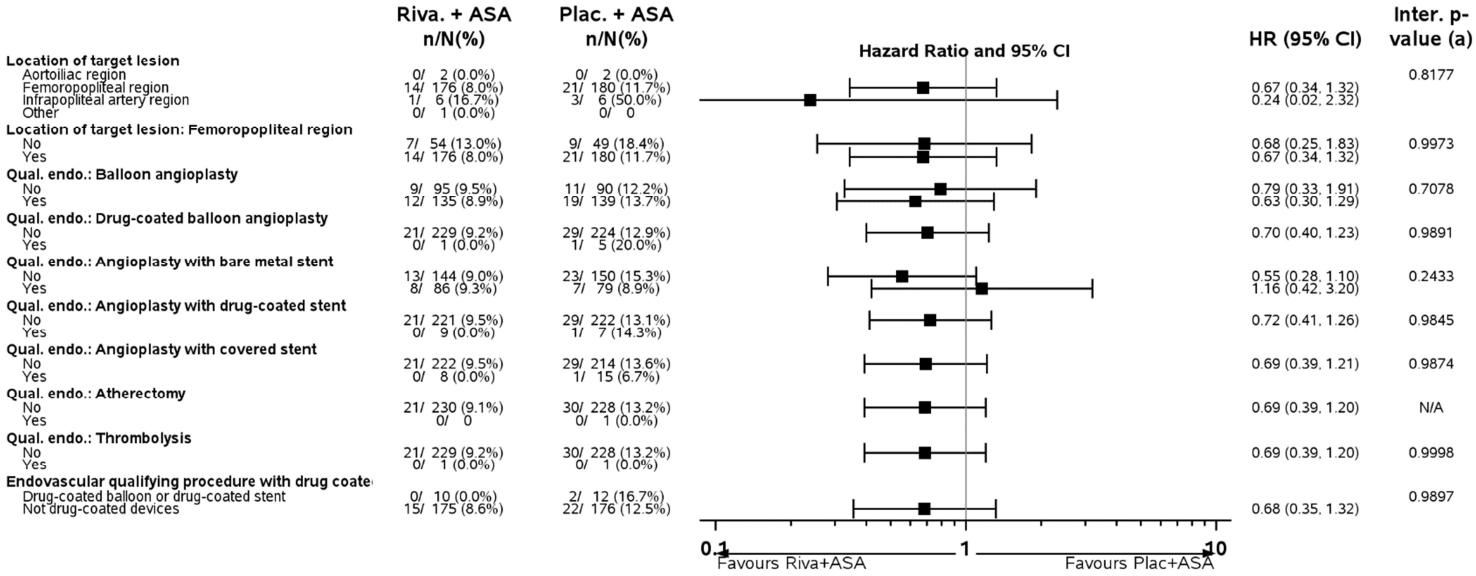
図 2.7.3.7-7 MI、虚血性脳卒中、冠動脈性心疾患死、ALI、又は血管系の原因による大切断の複合エンドポイントの Forest プロット（試験 17454、日本人集団、ITT、ECOD まで、ICAC 判定）




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 13/ 114 (11.4%) 18/ 114 (15.8%) 0.71 (0.35, 1.45) 0.9765
<= 30 days 5/ 63 (7.9%) 8/ 63 (12.7%) 0.62 (0.20, 1.88)
> 30 days 3/ 51 (5.9%) 4/ 49 (8.2%) 0.70 (0.16, 3.13)
Weight group (cut-off 60 kg)
<=60 kg 10/ 128 (7.8%) 18/ 136 (13.2%) 0.58 (0.27, 1.26) 0.4677
>60 kg 11/ 100 (11.0%) 12/ 92 (13.0%) 0.88 (0.39, 2.01)
eGFR (cut-offs: 60 ml/min/1.73m2)
<60 ml/min/1.73m2 13/ 106 (12.3%) 14/ 78 (17.9%) 0.69 (0.32, 1.47) 0.8140
>=60 ml/min/1.73m2 8/ 124 (6.5%) 16/ 151 (10.6%) 0.59 (0.25, 1.39)
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%) 0.0483
30 - <60 ml/min/1.73m2 12/ 105 (11.4%) 12/ 74 (16.2%) 0.71 (0.32, 1.59)
>=60 ml/min/1.73m2 8/ 124 (6.5%) 16/ 151 (10.6%) 0.59 (0.25, 1.39)
eGFR (cut-offs: 30, 50 and 80 ml/min/1.73m2)
<30 ml/min/1.73m2 1/ 1 (100.0%) 2/ 4 (50.0%) 0.0403
30 - 50 ml/min/1.73m2 6/ 54 (11.1%) 4/ 30 (13.3%) 0.88 (0.25, 3.13)
>50 - 80 ml/min/1.73m2 10/ 128 (7.8%) 21/ 142 (14.8%) 0.48 (0.23, 1.02)
>80 ml/min/1.73m2 4/ 47 (8.5%) 3/ 53 (5.7%) 1.68 (0.38, 7.53)
Fragile subjects
No 8/ 99 (8.1%) 10/ 107 (9.3%) 0.86 (0.34, 2.18) 0.5245
Yes 13/ 131 (9.9%) 20/ 122 (16.4%) 0.59 (0.30, 1.19)
Prior coronary artery disease
No 15/ 141 (10.6%) 16/ 149 (10.7%) 1.00 (0.49, 2.02) 0.0928
Yes 6/ 89 (6.7%) 14/ 80 (17.5%) 0.36 (0.14, 0.93)
Prior MI
No 19/ 211 (9.0%) 28/ 212 (13.2%) 0.67 (0.37, 1.20) 0.7213
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 12/ 128 (9.4%) 11/ 128 (8.6%) 1.13 (0.50, 2.56) 0.0972
Yes 9/ 102 (8.8%) 19/ 101 (18.8%) 0.43 (0.19, 0.95)
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 17/ 207 (8.2%) 29/ 218 (13.3%) 0.61 (0.34, 1.11) 0.3892
Yes 4/ 23 (17.4%) 1/ 11 (9.1%) 1.72 (0.19, 15.47)
History of heart failure
No 19/ 217 (8.8%) 29/ 219 (13.2%) 0.65 (0.37, 1.16) 0.5263
Yes 2/ 13 (15.4%) 1/ 10 (10.0%) 1.44 (0.13, 15.96)
Diabetes mellitus
No 13/ 124 (10.5%) 12/ 120 (10.0%) 1.09 (0.50, 2.39) 0.1193
Yes 8/ 106 (7.5%) 18/ 109 (16.5%) 0.44 (0.19, 1.01)
Smoking status
NEVER 5/ 40 (12.5%) 4/ 32 (12.5%) 0.97 (0.26, 3.61) 0.3139
FORMER 8/ 126 (6.3%) 19/ 139 (13.7%) 0.44 (0.19, 1.01)
CURRENT 8/ 64 (12.5%) 7/ 58 (12.1%) 1.11 (0.40, 3.07)
Hypertension
No 1/ 42 (2.4%) 9/ 40 (22.5%) 0.10 (0.01, 0.78) 0.0430
Yes 20/ 188 (10.6%) 21/ 189 (11.1%) 0.95 (0.51, 1.74)
Hyperlipidemia
No 7/ 92 (7.6%) 15/ 92 (16.3%) 0.46 (0.19, 1.13) 0.2300
Yes 14/ 138 (10.1%) 15/ 137 (10.9%) 0.92 (0.44, 1.91)
ABI/TBI categories at baseline (Month 1 visit)
ABI <= 0.80 or TBI <= 0.60 6/ 44 (13.6%) 7/ 27 (25.9%) 0.44 (0.15, 1.31) 0.7779
ABI > 0.80 and/or TBI > 0.60 15/ 179 (8.4%) 23/ 201 (11.4%) 0.72 (0.37, 1.37)
TBI and ABI not done 0/ 7 (0.0%) 0/ 1 (0.0%)
Weight group (cut-offs: 70 and 90 kg)
<=70 kg 17/ 196 (8.7%) 30/ 203 (14.8%) 0.58 (0.32, 1.05) 0.7775
>70 - <=90 kg 4/ 31 (12.9%) 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%) 9/ 51 (17.6%) 0.12 (0.02, 0.96) 0.0626
>=50 kg 20/ 189 (10.6%) 21/ 177 (11.9%) 0.92 (0.50, 1.70)
Weight group (cut-offs: 50, 70 and 90 kg)
<=50 kg 1/ 39 (2.6%) 9/ 52 (17.3%) 0.12 (0.02, 0.98) 0.3489
50 - <=70 kg 16/ 157 (10.2%) 21/ 151 (13.9%) 0.77 (0.40, 1.47)
70 - <=90 kg 4/ 31 (12.9%) 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%) 2/ 8 (25.0%) 2.85 (0.25, 32.09) 0.2092
30-<50 mL/min 6/ 71 (8.5%) 10/ 46 (21.7%) 0.36 (0.13, 1.00)
50-80 mL/min 9/ 109 (8.3%) 13/ 116 (11.2%) 0.71 (0.30, 1.65)
>80mL/min 5/ 45 (11.1%) 5/ 58 (8.6%) 1.40 (0.40, 4.84)
0.1
1
10
Favours Riva+ASA
Favours Plac+ASA

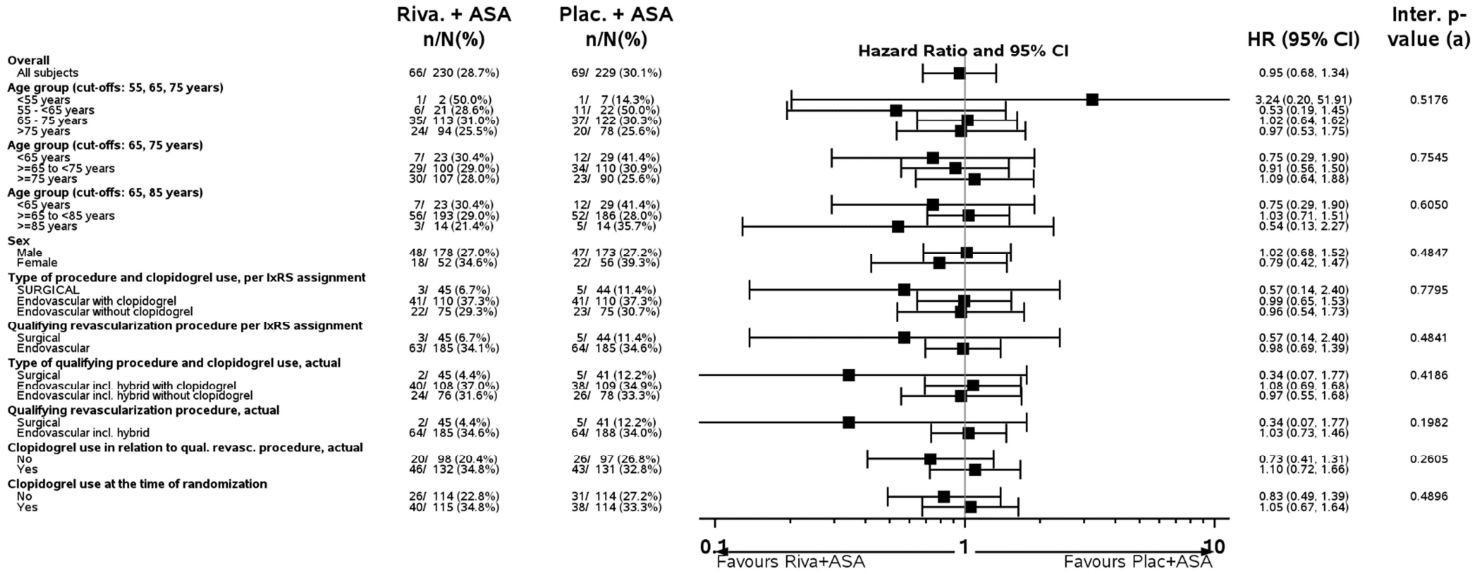

Riva. + ASA n/N(%)
Plac. + ASA n/N(%)
Hazard Ratio and 95% CI
HR (95% CI)
Inter. p-value (a)
Creatinine Clearance Group (cut-offs: 15, 30, 50, 80 mL/min) 0.2476
<15 mL/min 0/ 0 0/ 1 (0.0%) 2.45 (0.22, 27.61)
15-<30 mL/min 1/ 3 (33.3%) 2/ 7 (28.6%) 0.36 (0.13, 1.00)
30-<50 mL/min 6/ 71 (8.5%) 10/ 46 (21.7%) 0.71 (0.30, 1.65)
50-80 mL/min 9/ 199 (8.3%) 13/ 118 (11.2%) 1.40 (0.40, 4.84)
>80 mL/min 5/ 45 (11.1%) 5/ 58 (8.6%)
Clopidogrel use with study ASA after randomization 0.9710
None 13/ 114 (11.4%) 18/ 114 (15.8%) 0.71 (0.35, 1.45)
>0 - <=30 days 5/ 63 (7.9%) 8/ 63 (12.7%) 0.62 (0.20, 1.88)
>30 - <=60 days 0/ 15 (0.0%) 1/ 19 (5.3%) 1.25 (0.21, 7.51)
>60 - <=180 days 3/ 24 (12.5%) 2/ 22 (9.1%)
>180 days 0/ 11 (0.0%) 1/ 8 (12.5%)
Atrial fibrillation disease history 0.9998
No 21/ 224 (9.4%) 30/ 226 (13.3%) 0.70 (0.40, 1.22)
Yes 0/ 6 (0.0%) 0/ 3 (0.0%)
Atrial flutter disease history N/A
No 21/ 230 (9.1%) 30/ 229 (13.1%) 0.69 (0.39, 1.20)
Critical limb ischemia 0.6593
No 14/ 197 (7.1%) 19/ 198 (9.6%) 0.73 (0.36, 1.45)
Yes 7/ 33 (21.2%) 11/ 31 (35.5%) 0.55 (0.21, 1.42)
Critical leg ischemia categories 0.5555
No critical leg ischemia 14/ 197 (7.1%) 19/ 198 (9.6%) 0.73 (0.36, 1.45)
Critical leg ischemia history 2/ 15 (13.3%) 6/ 14 (42.9%) 0.30 (0.06, 1.51)
Critical leg ischemia ongoing 5/ 18 (27.8%) 5/ 17 (29.4%) 0.85 (0.25, 2.95)
Length of target lesion on the index leg 0.8190
SHORT (< 5 CM) 5/ 70 (7.1%) 4/ 56 (7.1%) 0.95 (0.25, 3.53)
INTERMEDIATE (5 CM TO < 15 CM) 4/ 73 (5.5%) 9/ 82 (11.0%) 0.53 (0.16, 1.72)
LONG (>= 15 CM) 12/ 87 (13.8%) 17/ 91 (18.7%) 0.70 (0.33, 1.46)
Time from qualifying revasc. procedure to randomization 0.7849
< Median (Days) 9/ 132 (6.8%) 13/ 120 (10.8%) 0.64 (0.27, 1.49)
>= Median (Days) 12/ 98 (12.2%) 17/ 109 (15.6%) 0.74 (0.35, 1.56)
Statin use during study 0.6744
No 7/ 84 (8.3%) 12/ 84 (14.3%) 0.59 (0.23, 1.50)
Yes 14/ 146 (9.6%) 18/ 145 (12.4%) 0.75 (0.37, 1.51)
PAD symptom status (Rutherford score) (<=2, 3, >=4) 0.9241
<=2 7/ 97 (7.2%) 12/ 107 (11.2%) 0.63 (0.25, 1.60)
3 7/ 106 (6.6%) 10/ 98 (10.2%) 0.63 (0.24, 1.67)
>=4 7/ 27 (25.9%) 8/ 24 (33.3%) 0.78 (0.28, 2.17)
PAD symptom status (Rutherford score) (<=2, 3, 4, >=5) 0.9690
<=2 7/ 97 (7.2%) 12/ 107 (11.2%) 0.63 (0.25, 1.60)
3 7/ 106 (6.6%) 10/ 98 (10.2%) 0.63 (0.24, 1.67)
4 4/ 13 (30.8%) 5/ 11 (45.5%) 0.79 (0.21, 2.93)
>= 5 3/ 14 (21.4%) 3/ 13 (23.1%) 0.92 (0.18, 4.78)
0.1
1
10
Favours Riva+ASA
Favours Plac+ASA

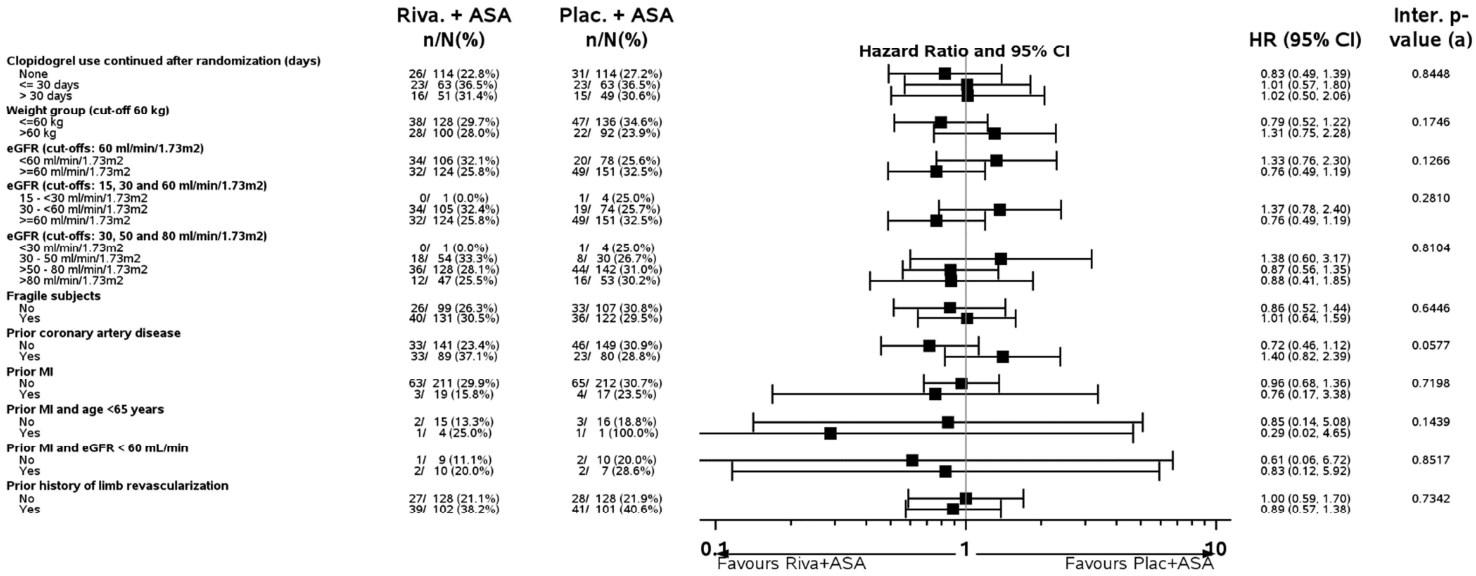


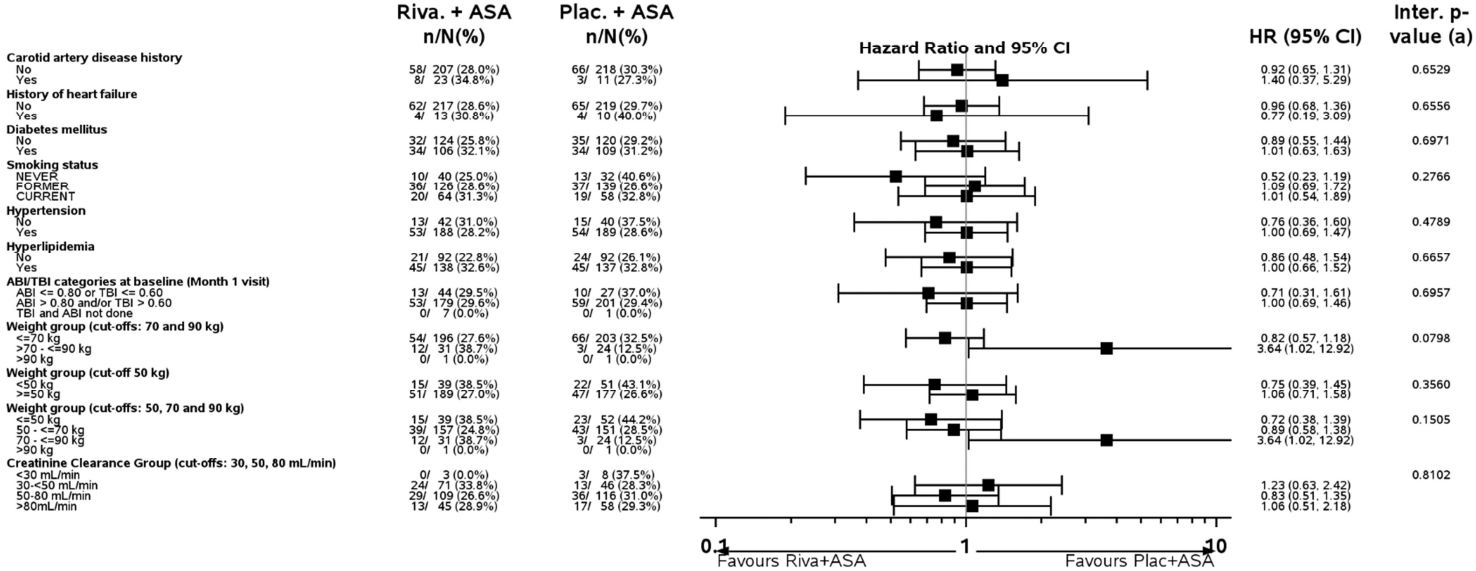
The ITT analysis set includes all randomized subjects. The ITT data scope includes outcome events observed from randomization date until efficacy cut-off date. Subgroup variables from Atrial fibrillation disease history and below are added post-hoc.
MI, stroke, mortality, ALI, major amputation of vascular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

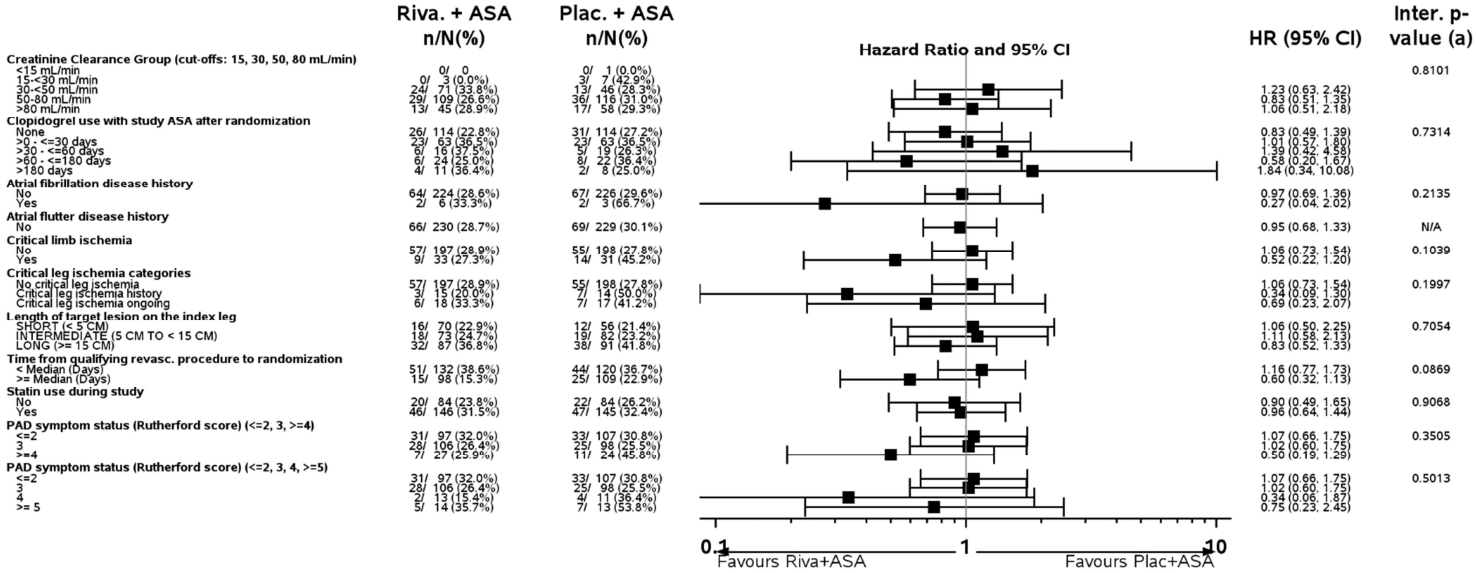
Source: 5.3.5.1.2 17454_J_analysis/Figure 14.2.5.2/4

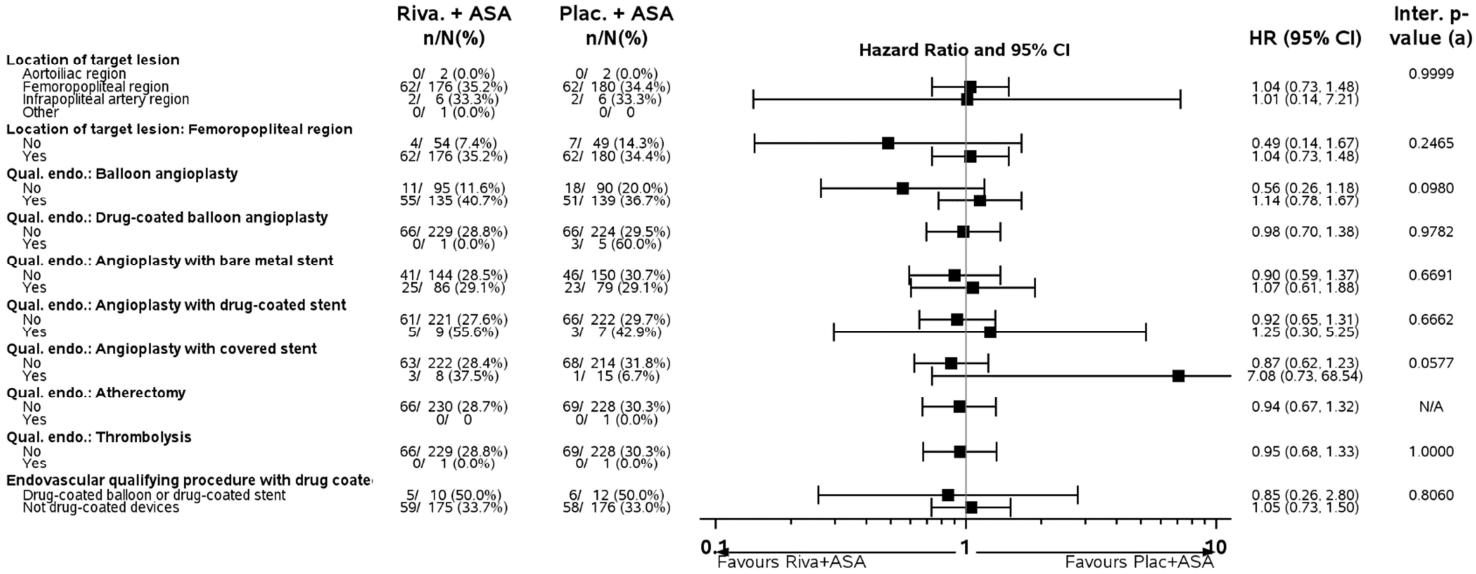
図 2.7.3.7-8 再発性肢虚血のために施行される、あらかじめ計画されていなかったインデックス肢に対する血行再建術の Forest プロット〔試験 17454、日本人集団、ITT、ECOD まで、治験責任（分担）医師判定〕




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 26/ 114 (22.8%) 31/ 114 (27.2%) 0.83 (0.49, 1.39) 0.8448
<= 30 days 23/ 63 (36.5%) 23/ 63 (36.5%) 1.01 (0.57, 1.80)
> 30 days 16/ 51 (31.4%) 15/ 49 (30.6%) 1.02 (0.50, 2.06)
Weight group (cut-off 60 kg)
<=60 kg 38/ 128 (29.7%) 47/ 136 (34.6%) 0.79 (0.52, 1.22) 0.1746
>60 kg 28/ 100 (28.0%) 22/ 92 (23.9%) 1.31 (0.75, 2.28)
eGFR (cut-offs: 60 ml/min/1.73m2)
<60 ml/min/1.73m2 34/ 106 (32.1%) 20/ 78 (25.6%) 1.33 (0.76, 2.30) 0.1266
>=60 ml/min/1.73m2 32/ 124 (25.8%) 49/ 151 (32.5%) 0.76 (0.49, 1.19)
eGFR (cut-offs: 15, 30 and 60 ml/min/1.73m2)
15 - <30 ml/min/1.73m2 0/ 1 (0.0%) 1/ 4 (25.0%) 0.2810
30 - <60 ml/min/1.73m2 34/ 105 (32.4%) 19/ 74 (25.7%) 1.37 (0.78, 2.40)
>=60 ml/min/1.73m2 32/ 124 (25.8%) 49/ 151 (32.5%) 0.76 (0.49, 1.19)
eGFR (cut-offs: 30, 50 and 80 ml/min/1.73m2)
<30 ml/min/1.73m2 0/ 1 (0.0%) 1/ 4 (25.0%) 0.8104
30 - 50 ml/min/1.73m2 18/ 54 (33.3%) 8/ 30 (26.7%) 1.38 (0.60, 3.17)
>50 - 80 ml/min/1.73m2 36/ 128 (28.1%) 44/ 142 (31.0%) 0.87 (0.56, 1.35)
>80 ml/min/1.73m2 12/ 47 (25.5%) 16/ 53 (30.2%) 0.88 (0.41, 1.85)
Fragile subjects
No 26/ 99 (26.3%) 33/ 107 (30.8%) 0.86 (0.52, 1.44) 0.6446
Yes 40/ 131 (30.5%) 36/ 122 (29.5%) 1.01 (0.64, 1.59)
Prior coronary artery disease
No 33/ 141 (23.4%) 46/ 149 (30.9%) 0.72 (0.46, 1.12) 0.0577
Yes 33/ 89 (37.1%) 23/ 80 (28.8%) 1.40 (0.82, 2.39)
Prior MI
No 63/ 211 (29.9%) 65/ 212 (30.7%) 0.96 (0.68, 1.36) 0.7198
Yes 3/ 19 (15.8%) 4/ 17 (23.5%) 0.76 (0.17, 3.38)
Prior MI and age <65 years
No 2/ 15 (13.3%) 3/ 16 (18.8%) 0.85 (0.14, 5.08) 0.1439
Yes 1/ 4 (25.0%) 1/ 1 (100.0%) 0.29 (0.02, 4.65)
Prior MI and eGFR < 60 mL/min
No 1/ 9 (11.1%) 2/ 10 (20.0%) 0.61 (0.06, 6.72) 0.8517
Yes 2/ 10 (20.0%) 2/ 7 (28.6%) 0.83 (0.12, 5.92)
Prior history of limb revascularization
No 27/ 128 (21.1%) 28/ 128 (21.9%) 1.00 (0.59, 1.70) 0.7342
Yes 39/ 102 (38.2%) 41/ 101 (40.6%) 0.89 (0.57, 1.38)
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 58/ 207 (28.0%) 66/ 218 (30.3%) 0.92 (0.65, 1.31)
Yes 8/ 23 (34.8%) 3/ 11 (27.3%) 1.40 (0.37, 5.29) 0.6529
History of heart failure
No 62/ 217 (28.6%) 65/ 219 (29.7%) 0.96 (0.68, 1.36)
Yes 4/ 13 (30.8%) 4/ 10 (40.0%) 0.77 (0.19, 3.09) 0.6556
Diabetes mellitus
No 32/ 124 (25.8%) 35/ 120 (29.2%) 0.89 (0.55, 1.44)
Yes 34/ 106 (32.1%) 34/ 109 (31.2%) 1.01 (0.63, 1.63) 0.6971
Smoking status
NEVER 10/ 40 (25.0%) 13/ 32 (40.6%) 0.52 (0.23, 1.19)
FORMER 36/ 126 (28.6%) 37/ 139 (26.6%) 1.09 (0.69, 1.72)
CURRENT 20/ 64 (31.3%) 19/ 58 (32.8%) 1.01 (0.54, 1.89) 0.2766
Hypertension
No 13/ 42 (31.0%) 15/ 40 (37.5%) 0.76 (0.36, 1.60)
Yes 53/ 188 (28.2%) 54/ 189 (28.6%) 1.00 (0.69, 1.47) 0.4789
Hyperlipidemia
No 21/ 92 (22.8%) 24/ 92 (26.1%) 0.86 (0.48, 1.54)
Yes 45/ 138 (32.6%) 45/ 137 (32.8%) 1.00 (0.66, 1.52) 0.6657
ABI/TBI categories at baseline (Month 1 visit)
ABI <= 0.80 or TBI <= 0.60 13/ 44 (29.5%) 10/ 27 (37.0%) 0.71 (0.31, 1.61)
ABI > 0.80 and/or TBI > 0.60 53/ 179 (29.6%) 59/ 201 (29.4%) 1.00 (0.69, 1.46)
TBI and ABI not done 0/ 7 (0.0%) 0/ 1 (0.0%) 0.6957
Weight group (cut-offs: 70 and 90 kg)
<=70 kg 54/ 196 (27.6%) 66/ 203 (32.5%) 0.82 (0.57, 1.18)
>70 - <=90 kg 12/ 31 (38.7%) 3/ 24 (12.5%) 3.64 (1.02, 12.92)
>90 kg 0/ 1 (0.0%) 0/ 1 (0.0%) 0.0798
Weight group (cut-off 50 kg)
<50 kg 15/ 39 (38.5%) 22/ 51 (43.1%) 0.75 (0.39, 1.45)
>=50 kg 51/ 189 (27.0%) 47/ 177 (26.6%) 1.06 (0.71, 1.58) 0.3560
Weight group (cut-offs: 50, 70 and 90 kg)
<=50 kg 15/ 39 (38.5%) 23/ 52 (44.2%) 0.72 (0.38, 1.39)
50 - <=70 kg 39/ 157 (24.8%) 43/ 151 (28.5%) 0.89 (0.58, 1.38)
70 - <=90 kg 12/ 31 (38.7%) 3/ 24 (12.5%) 3.64 (1.02, 12.92)
>90 kg 0/ 1 (0.0%) 0/ 1 (0.0%) 0.1505
Creatinine Clearance Group (cut-offs: 30, 50, 80 mL/min)
<30 mL/min 0/ 3 (0.0%) 3/ 8 (37.5%)
30-<50 mL/min 24/ 71 (33.8%) 13/ 46 (28.3%) 1.23 (0.63, 2.42)
50-80 mL/min 29/ 109 (26.6%) 36/ 116 (31.0%) 0.83 (0.51, 1.35)
>80mL/min 13/ 45 (28.9%) 17/ 58 (29.3%) 1.06 (0.51, 2.18) 0.8102
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) 0.8101
<15 mL/min 0/ 0 0/ 1 (0.0%)
15-<30 mL/min 0/ 3 (0.0%) 3/ 7 (42.9%)
30-<50 mL/min 24/ 71 (33.8%) 13/ 46 (28.3%) 1.23 (0.63, 2.42)
50-80 mL/min 29/ 109 (26.6%) 36/ 116 (31.0%) 0.83 (0.51, 1.35)
>80 mL/min 13/ 45 (28.9%) 17/ 58 (29.3%) 1.06 (0.51, 2.18)
Clopidogrel use with study ASA after randomization 0.7314
None 26/ 114 (22.8%) 31/ 114 (27.2%) 0.83 (0.49, 1.39)
>0 - <=30 days 23/ 63 (36.5%) 23/ 63 (36.5%) 1.01 (0.57, 1.80)
>30 - <=60 days 6/ 16 (37.5%) 5/ 19 (26.3%) 1.39 (0.42, 4.58)
>60 - <=180 days 6/ 24 (25.0%) 8/ 22 (36.4%) 0.58 (0.20, 1.67)
>180 days 4/ 11 (36.4%) 2/ 8 (25.0%) 1.84 (0.34, 10.08)
Atrial fibrillation disease history 0.2135
No 64/ 224 (28.6%) 67/ 226 (29.6%) 0.97 (0.69, 1.36)
Yes 2/ 6 (33.3%) 2/ 3 (66.7%) 0.27 (0.04, 2.02)
Atrial flutter disease history
No 66/ 230 (28.7%) 69/ 229 (30.1%) 0.95 (0.68, 1.33) N/A
Critical limb ischemia 0.1039
No 57/ 197 (28.9%) 55/ 198 (27.8%) 1.06 (0.73, 1.54)
Yes 9/ 33 (27.3%) 14/ 31 (45.2%) 0.52 (0.22, 1.20)
Critical leg ischemia categories 0.1997
No critical leg ischemia 57/ 197 (28.9%) 55/ 198 (27.8%) 1.06 (0.73, 1.54)
Critical leg ischemia history 3/ 15 (20.0%) 7/ 14 (50.0%) 0.34 (0.09, 1.30)
Critical leg ischemia ongoing 6/ 18 (33.3%) 7/ 17 (41.2%) 0.69 (0.23, 2.07)
Length of target lesion on the index leg 0.7054
SHORT (< 5 CM) 16/ 70 (22.9%) 12/ 56 (21.4%) 1.06 (0.50, 2.25)
INTERMEDIATE (5 CM TO < 15 CM) 18/ 73 (24.7%) 19/ 82 (23.2%) 1.11 (0.58, 2.13)
LONG (>= 15 CM) 32/ 87 (36.8%) 38/ 91 (41.8%) 0.83 (0.52, 1.33)
Time from qualifying revasc. procedure to randomization 0.0869
< Median (Days) 51/ 132 (38.6%) 44/ 120 (36.7%) 1.16 (0.77, 1.73)
>= Median (Days) 15/ 98 (15.3%) 25/ 109 (22.9%) 0.60 (0.32, 1.13)
Statin use during study 0.9068
No 20/ 84 (23.8%) 22/ 84 (26.2%) 0.90 (0.49, 1.65)
Yes 46/ 146 (31.5%) 47/ 145 (32.4%) 0.96 (0.64, 1.44)
PAD symptom status (Rutherford score) (<=2, 3, >=4) 0.3505
<=2 31/ 97 (32.0%) 33/ 107 (30.8%) 1.07 (0.66, 1.75)
3 28/ 106 (26.4%) 25/ 98 (25.5%) 1.02 (0.60, 1.75)
>=4 7/ 27 (25.9%) 11/ 24 (45.8%) 0.50 (0.19, 1.29)
PAD symptom status (Rutherford score) (<=2, 3, 4, >=5) 0.5013
<=2 31/ 97 (32.0%) 33/ 107 (30.8%) 1.07 (0.66, 1.75)
3 28/ 106 (26.4%) 25/ 98 (25.5%) 1.02 (0.60, 1.75)
4 2/ 13 (15.4%) 4/ 11 (36.4%) 0.34 (0.06, 1.87)
>= 5 5/ 14 (35.7%) 7/ 13 (53.8%) 0.75 (0.23, 2.45)
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 14.2.5.2/22