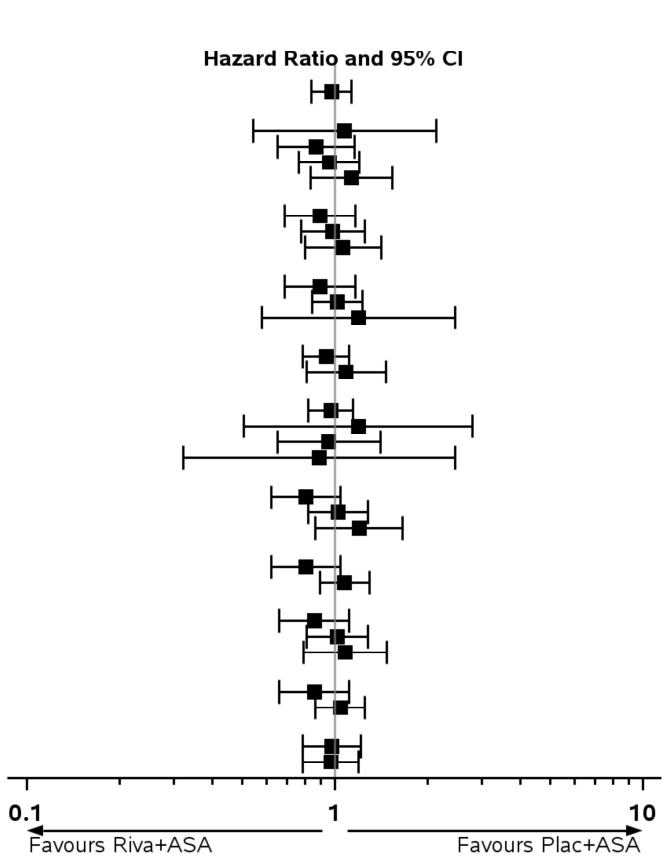
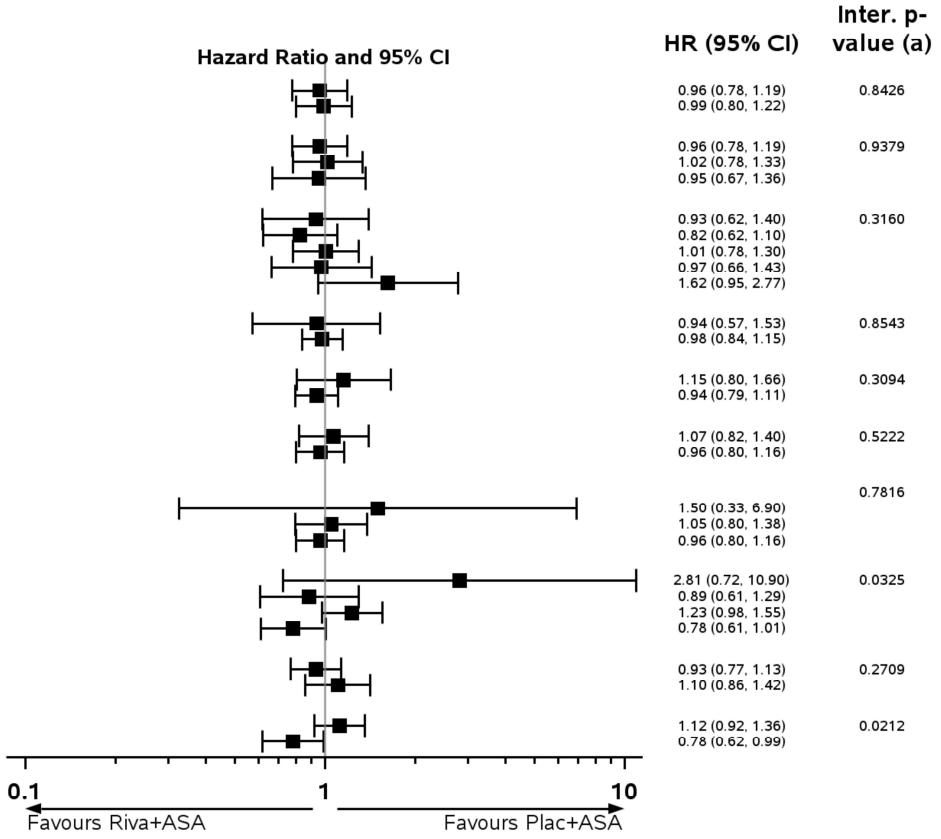
図 2.7.3.7-18 MACE の Forest プロット（試験 17454、全体集団、ITT、ECOD まで、ICAC 判定）

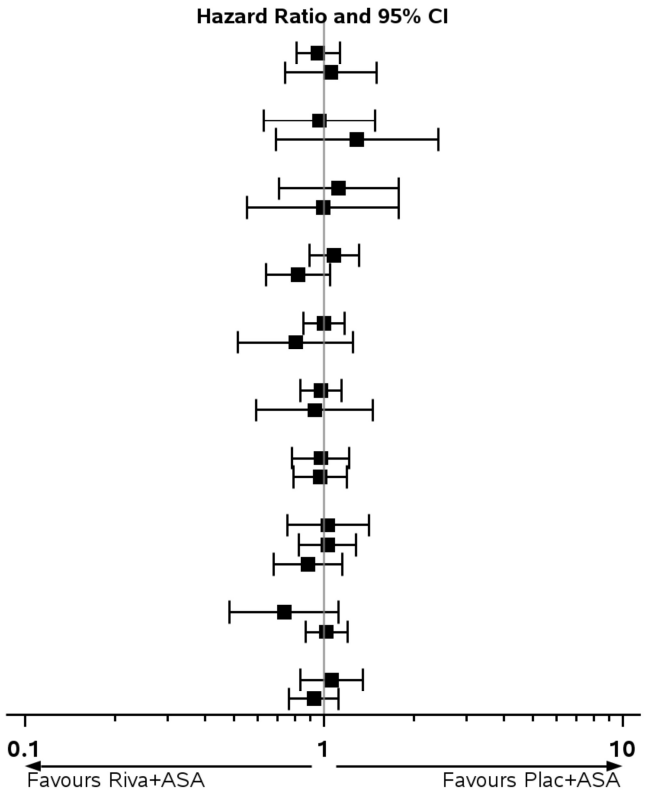
	Riva. + ASA n/N(%)	Plac. + ASA n/N(%)	HR (95% CI)	Inter. p-value (a)
Overall				
All subjects	338/ 3286 (10.3%)	346/ 3278 (10.6%)	0.97 (0.84, 1.13)	
Age group (cut-offs: 55, 65, 75 years)				
<55 years	17/ 220 (7.7%)	16/ 221 (7.2%)	1.07 (0.54, 2.13)	0.6284
55 - <65 years	90/ 1129 (8.0%)	95/ 1052 (9.0%)	0.87 (0.65, 1.16)	
65 - 75 years	142/ 1367 (10.4%)	156/ 1437 (10.9%)	0.96 (0.76, 1.20)	
>75 years	89/ 570 (15.6%)	79/ 568 (13.9%)	1.13 (0.84, 1.53)	
Age group (cut-offs: 65, 75 years)				
<65 years	107/ 1349 (7.9%)	111/ 1273 (8.7%)	0.89 (0.69, 1.17)	0.6727
>=65 to <75 years	132/ 1264 (10.4%)	143/ 1348 (10.6%)	0.98 (0.78, 1.25)	
>=75 years	99/ 673 (14.7%)	92/ 657 (14.0%)	1.06 (0.80, 1.41)	
Age group (cut-offs: 65, 85 years)				
<65 years	107/ 1349 (7.9%)	111/ 1273 (8.7%)	0.89 (0.69, 1.17)	0.6731
>=65 to <85 years	216/ 1867 (11.6%)	220/ 1934 (11.4%)	1.02 (0.84, 1.23)	
>=85 years	15/ 70 (21.4%)	15/ 71 (21.1%)	1.19 (0.58, 2.46)	
Sex				
Male	247/ 2439 (10.1%)	261/ 2421 (10.8%)	0.94 (0.79, 1.11)	0.3862
Female	91/ 847 (10.7%)	85/ 857 (9.9%)	1.09 (0.81, 1.46)	
Race Group				
White	267/ 2647 (10.1%)	275/ 2656 (10.4%)	0.97 (0.82, 1.15)	0.9527
Black	13/ 84 (15.5%)	9/ 71 (12.7%)	1.19 (0.51, 2.80)	
Asian	51/ 484 (10.5%)	54/ 482 (11.2%)	0.96 (0.65, 1.40)	
Other	7/ 71 (9.9%)	8/ 69 (11.6%)	0.89 (0.32, 2.46)	
Type of procedure and clopidogrel use, per IxRS assignment				
SURGICAL	104/ 1133 (9.2%)	128/ 1138 (11.2%)	0.80 (0.62, 1.04)	0.1474
Endovascular with clopidogrel	155/ 1539 (10.1%)	152/ 1541 (9.9%)	1.02 (0.82, 1.28)	
Endovascular without clopidogrel	79/ 614 (12.9%)	66/ 599 (11.0%)	1.20 (0.86, 1.66)	
Qualifying revascularization procedure per IxRS assignment				
Surgical	104/ 1133 (9.2%)	128/ 1138 (11.2%)	0.80 (0.62, 1.04)	0.0733
Endovascular	234/ 2153 (10.9%)	218/ 2140 (10.2%)	1.08 (0.89, 1.29)	
Type of qualifying procedure and clopidogrel use, actual				
Surgical	104/ 1084 (9.6%)	122/ 1101 (11.1%)	0.86 (0.66, 1.11)	0.4690
Endovascular incl. hybrid with clopidogrel	151/ 1505 (10.0%)	148/ 1499 (9.9%)	1.02 (0.81, 1.28)	
Endovascular incl. hybrid without clopidogrel	83/ 693 (12.0%)	76/ 673 (11.3%)	1.08 (0.79, 1.47)	
Qualifying revascularization procedure, actual				
Surgical	104/ 1084 (9.6%)	122/ 1101 (11.1%)	0.86 (0.66, 1.11)	0.2296
Endovascular incl. hybrid	234/ 2202 (10.6%)	224/ 2177 (10.3%)	1.04 (0.87, 1.25)	
Clopidogrel use in relation to qual. revasc. procedure, actual				
No	163/ 1555 (10.5%)	164/ 1520 (10.8%)	0.98 (0.79, 1.21)	0.9683
Yes	175/ 1729 (10.1%)	182/ 1751 (10.4%)	0.97 (0.79, 1.19)	



	Riva. + ASA n/N(%)	Plac. + ASA n/N(%)	HR (95% CI)	Inter. p-value (a)
Clopidogrel use at the time of randomization				
No	167/ 1621 (10.3%)	173/ 1613 (10.7%)	0.96 (0.78, 1.19)	0.8426
Yes	171/ 1658 (10.3%)	172/ 1655 (10.4%)	0.99 (0.80, 1.22)	
Clopidogrel use continued after randomization (days)				
None	167/ 1621 (10.3%)	173/ 1613 (10.7%)	0.96 (0.78, 1.19)	0.9379
<= 30 days	113/ 988 (11.4%)	104/ 935 (11.1%)	1.02 (0.78, 1.33)	
> 30 days	57/ 644 (8.9%)	64/ 678 (9.4%)	0.95 (0.67, 1.36)	
Geographic Region 1				
North America	45/ 347 (13.0%)	48/ 347 (13.8%)	0.93 (0.62, 1.40)	0.3160
Western Europe	87/ 914 (9.5%)	103/ 912 (11.3%)	0.82 (0.62, 1.10)	
Eastern Europe	121/ 1301 (9.3%)	120/ 1298 (9.2%)	1.01 (0.78, 1.30)	
Asia Pacific	51/ 481 (10.6%)	53/ 480 (11.0%)	0.97 (0.66, 1.43)	
South America	34/ 243 (14.0%)	22/ 241 (9.1%)	1.62 (0.95, 2.77)	
Geographic Region 3				
US	31/ 262 (11.8%)	33/ 262 (12.6%)	0.94 (0.57, 1.53)	0.8543
non-US	307/ 3024 (10.2%)	313/ 3016 (10.4%)	0.98 (0.84, 1.15)	
Weight group (cut-off 60 kg)				
<=60 kg	62/ 534 (11.6%)	56/ 547 (10.2%)	1.15 (0.80, 1.66)	0.3094
>60 kg	271/ 2716 (10.0%)	287/ 2700 (10.6%)	0.94 (0.79, 1.11)	
eGFR (cut-offs: 60 ml/min/1.73m2)				
<60 ml/min/1.73m2	108/ 661 (16.3%)	105/ 666 (15.8%)	1.07 (0.82, 1.40)	0.5222
>=60 ml/min/1.73m2	220/ 2499 (8.8%)	226/ 2493 (9.1%)	0.96 (0.80, 1.16)	
eGFR (cut-offs: 15, 30 and 60 ml/min/1.73m2)				
<15 ml/min/1.73m2	2/ 2 (100.0%)	0/ 0		0.7816
15 - <30 ml/min/1.73m2	3/ 13 (23.1%)	5/ 28 (17.9%)	1.50 (0.33, 6.90)	
30 - <60 ml/min/1.73m2	103/ 646 (15.9%)	100/ 638 (15.7%)	1.05 (0.80, 1.38)	
>=60 ml/min/1.73m2	220/ 2499 (8.8%)	226/ 2493 (9.1%)	0.96 (0.80, 1.16)	
eGFR (cut-offs: 30, 50 and 80 ml/min/1.73m2)				
<30 ml/min/1.73m2	5/ 15 (33.3%)	5/ 28 (17.9%)	2.81 (0.72, 10.90)	0.0325
30 - 50 ml/min/1.73m2	53/ 343 (15.5%)	55/ 308 (17.9%)	0.89 (0.61, 1.29)	
>50 - 80 ml/min/1.73m2	160/ 1367 (11.7%)	132/ 1369 (9.6%)	1.23 (0.98, 1.55)	
>80 ml/min/1.73m2	110/ 1435 (7.7%)	139/ 1454 (9.6%)	0.78 (0.61, 1.01)	
Fragile subjects				
No	201/ 2338 (8.6%)	213/ 2332 (9.1%)	0.93 (0.77, 1.13)	0.2709
Yes	128/ 835 (15.3%)	119/ 839 (14.2%)	1.10 (0.86, 1.42)	
Prior coronary artery disease				
No	212/ 2233 (9.5%)	193/ 2263 (8.5%)	1.12 (0.92, 1.36)	0.0212
Yes	126/ 1052 (12.0%)	153/ 1015 (15.1%)	0.78 (0.62, 0.99)	



	Riva. + ASA n/N(%)	Plac. + ASA n/N(%)	HR (95% CI)	Inter. p-value (a)
Prior MI				
No	273/ 2920 (9.3%)	286/ 2928 (9.8%)	0.96 (0.81, 1.13)	0.6556
Yes	65/ 365 (17.8%)	60/ 349 (17.2%)	1.05 (0.74, 1.50)	
Prior MI and age <65 years				
No	41/ 225 (18.2%)	43/ 229 (18.8%)	0.97 (0.63, 1.49)	0.4893
Yes	24/ 140 (17.1%)	17/ 120 (14.2%)	1.29 (0.69, 2.41)	
Prior MI and eGFR < 60 mL/min				
No	41/ 261 (15.7%)	33/ 225 (14.7%)	1.12 (0.71, 1.78)	0.7675
Yes	21/ 87 (24.1%)	25/ 103 (24.3%)	0.99 (0.55, 1.78)	
Prior history of limb revascularization				
No	222/ 2104 (10.6%)	209/ 2122 (9.8%)	1.08 (0.90, 1.31)	0.0751
Yes	116/ 1181 (9.8%)	137/ 1155 (11.9%)	0.82 (0.64, 1.05)	
Carotid artery disease history				
No	303/ 3002 (10.1%)	302/ 2982 (10.1%)	1.00 (0.85, 1.17)	0.3723
Yes	35/ 282 (12.4%)	44/ 293 (15.0%)	0.80 (0.51, 1.25)	
History of heart failure				
No	301/ 3017 (10.0%)	306/ 3005 (10.2%)	0.98 (0.83, 1.15)	0.9273
Yes	37/ 267 (13.9%)	40/ 272 (14.7%)	0.93 (0.59, 1.46)	
Diabetes mellitus				
No	157/ 1972 (8.0%)	161/ 1961 (8.2%)	0.97 (0.78, 1.21)	0.9988
Yes	181/ 1313 (13.8%)	185/ 1316 (14.1%)	0.97 (0.79, 1.19)	
Smoking status				
NEVER	76/ 662 (11.5%)	78/ 689 (11.3%)	1.03 (0.75, 1.42)	0.6594
FORMER	158/ 1475 (10.7%)	154/ 1456 (10.6%)	1.03 (0.82, 1.28)	
CURRENT	104/ 1147 (9.1%)	114/ 1132 (10.1%)	0.88 (0.68, 1.15)	
Hypertension				
No	37/ 601 (6.2%)	52/ 620 (8.4%)	0.73 (0.48, 1.12)	0.1335
Yes	301/ 2684 (11.2%)	294/ 2658 (11.1%)	1.02 (0.87, 1.20)	
Hyperlipidemia				
No	135/ 1313 (10.3%)	127/ 1310 (9.7%)	1.06 (0.83, 1.35)	0.3827
Yes	203/ 1971 (10.3%)	219/ 1968 (11.1%)	0.93 (0.76, 1.12)	



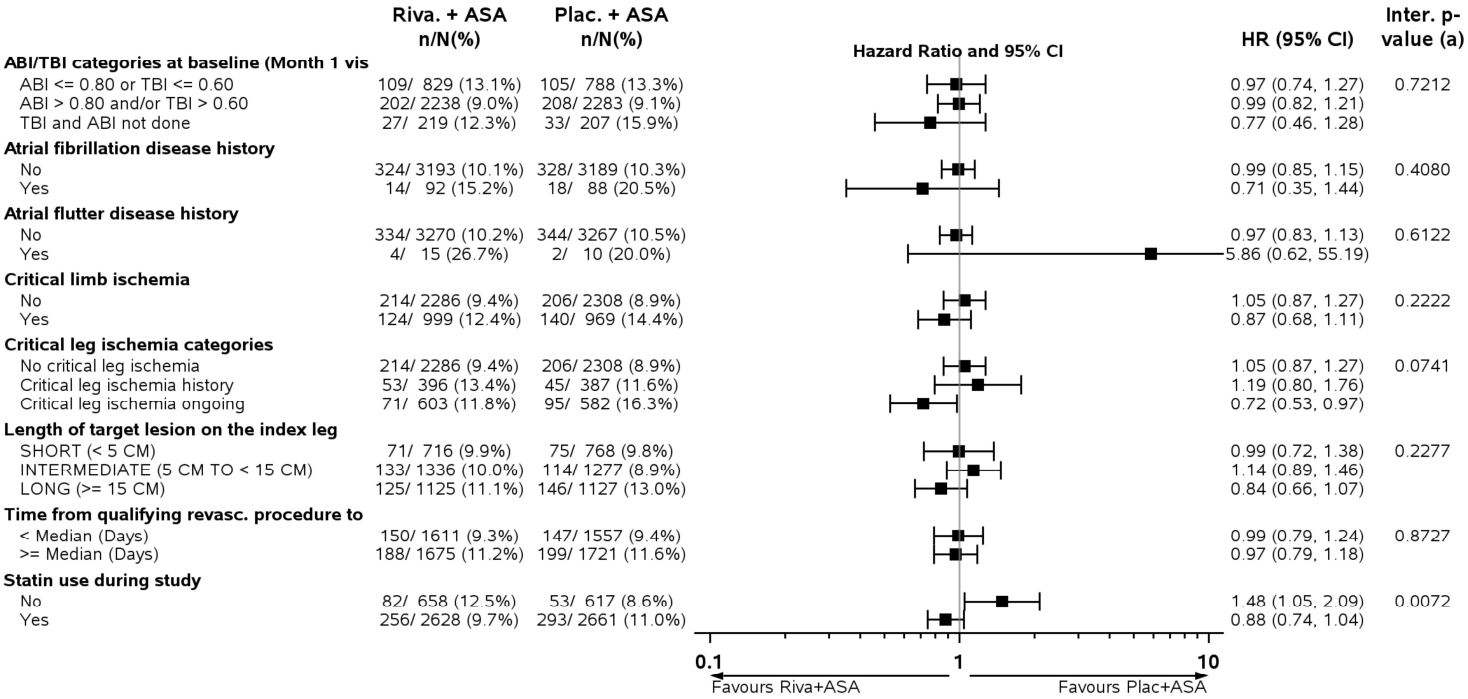
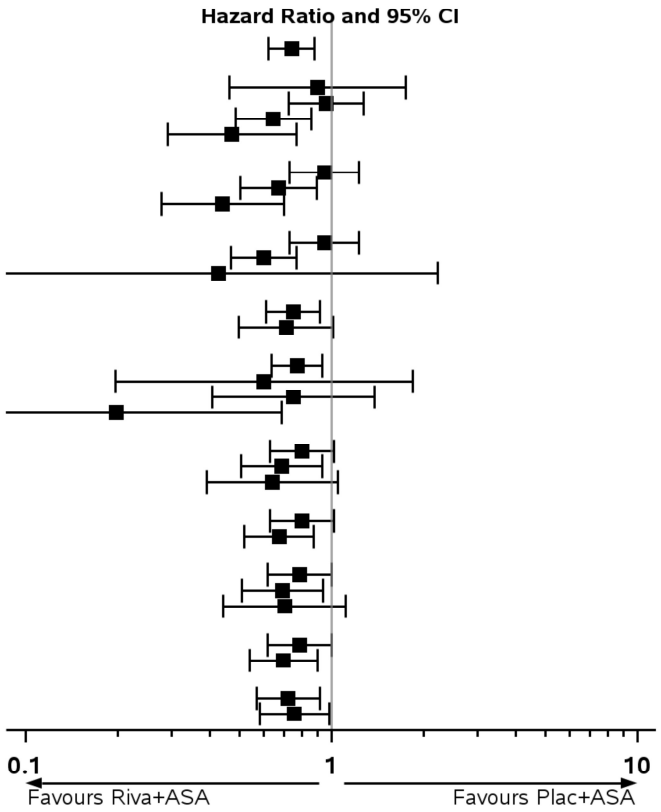


Figure displays outcome events meeting the definition as adjudicated by Independent Clinical Adjudication Committee (ICAC). Subgroup variables from Atrial fibrillation disease history and below are added post-hoc.
The ITT analysis set includes all randomized subjects. The ITT data scope includes outcome 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 Cox proportional hazards model stratified by type of procedure and clopidogrel use (per IxRS) (except for subgroups related to qualifying revascularization procedure or clopidogrel use), with treatment as the only covariate.
(a) P-value for interaction is based on the Cox proportional hazards model stratified by type of procedure and clopidogrel use (per IxRS) by adding the corresponding treatment interaction term.

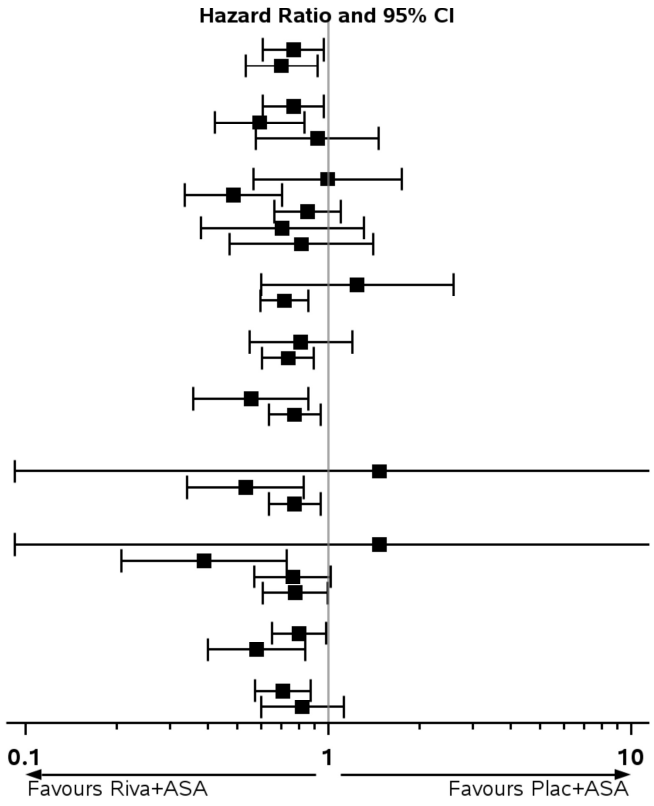
Source: 5.3.5.1.1 PH-40164/Figure 14.2.5.1/2

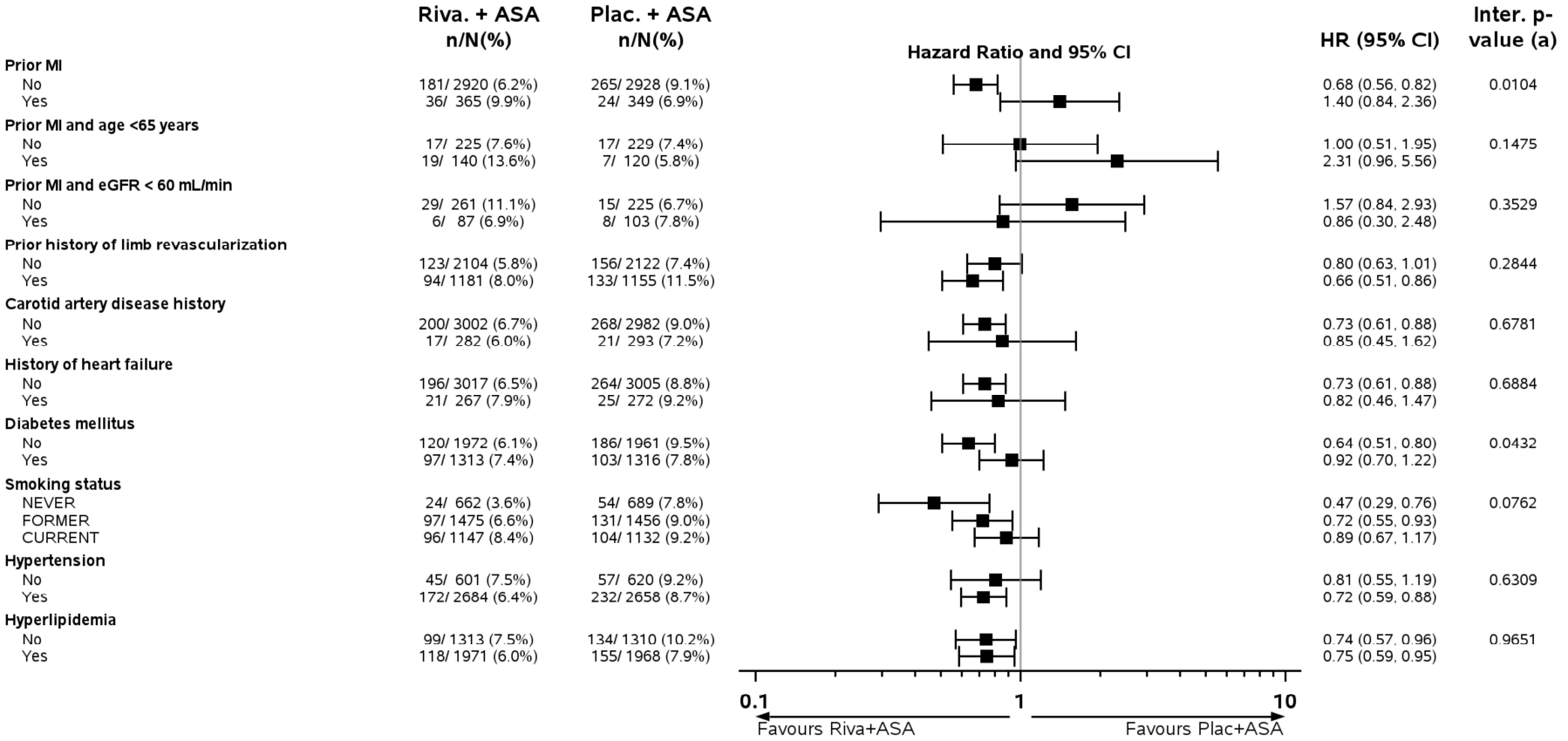
図 2.7.3.7-19 MALE の Forest プロット（試験 17454、全体集団、ITT、ECOD まで、ICAC 判定）

	Riva. + ASA n/N(%)	Plac. + ASA n/N(%)	HR (95% CI)	Inter. p-value (a)
Overall				
All subjects	217/ 3286 (6.6%)	289/ 3278 (8.8%)	0.74 (0.62, 0.88)	
Age group (cut-offs: 55, 65, 75 years)				
<55 years	17/ 220 (7.7%)	18/ 221 (8.1%)	0.90 (0.46, 1.75)	0.0505
55 - <65 years	98/ 1129 (8.7%)	94/ 1052 (8.9%)	0.96 (0.72, 1.27)	
65 - 75 years	78/ 1367 (5.7%)	125/ 1437 (8.7%)	0.65 (0.49, 0.86)	
>75 years	24/ 570 (4.2%)	52/ 568 (9.2%)	0.47 (0.29, 0.77)	
Age group (cut-offs: 65, 75 years)				
<65 years	115/ 1349 (8.5%)	112/ 1273 (8.8%)	0.95 (0.73, 1.23)	0.0128
>=65 to <75 years	76/ 1264 (6.0%)	118/ 1348 (8.8%)	0.67 (0.50, 0.90)	
>=75 years	26/ 673 (3.9%)	59/ 657 (9.0%)	0.44 (0.28, 0.70)	
Age group (cut-offs: 65, 85 years)				
<65 years	115/ 1349 (8.5%)	112/ 1273 (8.8%)	0.95 (0.73, 1.23)	0.0310
>=65 to <85 years	100/ 1867 (5.4%)	172/ 1934 (8.9%)	0.60 (0.47, 0.77)	
>=85 years	2/ 70 (2.9%)	5/ 71 (7.0%)	0.43 (0.08, 2.23)	
Sex				
Male	165/ 2439 (6.8%)	215/ 2421 (8.9%)	0.75 (0.61, 0.92)	0.7953
Female	52/ 847 (6.1%)	74/ 857 (8.6%)	0.71 (0.50, 1.01)	
Race Group				
White	190/ 2647 (7.2%)	244/ 2656 (9.2%)	0.77 (0.64, 0.93)	0.2261
Black	6/ 84 (7.1%)	7/ 71 (9.9%)	0.60 (0.20, 1.84)	
Asian	18/ 484 (3.7%)	24/ 482 (5.0%)	0.75 (0.41, 1.38)	
Other	3/ 71 (4.2%)	14/ 69 (20.3%)	0.20 (0.06, 0.69)	
Type of procedure and clopidogrel use, per IxRS assignment				
SURGICAL	122/ 1133 (10.8%)	149/ 1138 (13.1%)	0.80 (0.63, 1.02)	0.6216
Endovascular with clopidogrel	69/ 1539 (4.5%)	100/ 1541 (6.5%)	0.69 (0.50, 0.93)	
Endovascular without clopidogrel	26/ 614 (4.2%)	40/ 599 (6.7%)	0.64 (0.39, 1.05)	
Qualifying revascularization procedure per IxRS assignment				
Surgical	122/ 1133 (10.8%)	149/ 1138 (13.1%)	0.80 (0.63, 1.02)	0.3445
Endovascular	95/ 2153 (4.4%)	140/ 2140 (6.5%)	0.67 (0.52, 0.87)	
Type of qualifying procedure and clopidogrel use, actual				
Surgical	117/ 1084 (10.8%)	147/ 1101 (13.4%)	0.79 (0.62, 1.00)	0.7995
Endovascular incl. hybrid with clopidogrel	69/ 1505 (4.6%)	99/ 1499 (6.6%)	0.69 (0.51, 0.94)	
Endovascular incl. hybrid without clopidogrel	31/ 693 (4.5%)	43/ 673 (6.4%)	0.70 (0.44, 1.11)	
Qualifying revascularization procedure, actual				
Surgical	117/ 1084 (10.8%)	147/ 1101 (13.4%)	0.79 (0.62, 1.00)	0.5072
Endovascular incl. hybrid	100/ 2202 (4.5%)	142/ 2177 (6.5%)	0.70 (0.54, 0.90)	
Clopidogrel use in relation to qual. revasc. procedure, actual				
No	118/ 1555 (7.6%)	158/ 1520 (10.4%)	0.72 (0.57, 0.91)	0.7850
Yes	98/ 1729 (5.7%)	130/ 1751 (7.4%)	0.76 (0.58, 0.98)	



	Riva. + ASA n/N(%)	Plac. + ASA n/N(%)	HR (95% CI)	Inter. p-value (a)
Clopidogrel use at the time of randomization				
No	128/ 1621 (7.9%)	164/ 1613 (10.2%)	0.77 (0.61, 0.97)	0.6298
Yes	88/ 1658 (5.3%)	124/ 1655 (7.5%)	0.70 (0.53, 0.92)	
Clopidogrel use continued after randomization (days)				
None	128/ 1621 (7.9%)	164/ 1613 (10.2%)	0.77 (0.61, 0.97)	0.2834
<= 30 days	54/ 988 (5.5%)	84/ 935 (9.0%)	0.59 (0.42, 0.84)	
> 30 days	33/ 644 (5.1%)	38/ 678 (5.6%)	0.92 (0.58, 1.47)	
Geographic Region 1				
North America	24/ 347 (6.9%)	24/ 347 (6.9%)	0.99 (0.56, 1.75)	0.1151
Western Europe	42/ 914 (4.6%)	84/ 912 (9.2%)	0.48 (0.33, 0.70)	
Eastern Europe	111/ 1301 (8.5%)	128/ 1298 (9.9%)	0.85 (0.66, 1.10)	
Asia Pacific	17/ 481 (3.5%)	24/ 480 (5.0%)	0.70 (0.38, 1.31)	
South America	23/ 243 (9.5%)	29/ 241 (12.0%)	0.81 (0.47, 1.41)	
Geographic Region 3				
US	16/ 262 (6.1%)	13/ 262 (5.0%)	1.25 (0.60, 2.59)	0.1448
non-US	201/ 3024 (6.6%)	276/ 3016 (9.2%)	0.71 (0.60, 0.86)	
Weight group (cut-off 60 kg)				
<=60 kg	46/ 534 (8.6%)	57/ 547 (10.4%)	0.81 (0.55, 1.20)	0.6563
>60 kg	171/ 2716 (6.3%)	228/ 2700 (8.4%)	0.74 (0.60, 0.90)	
eGFR (cut-offs: 60 ml/min/1.73m2)				
<60 ml/min/1.73m2	31/ 661 (4.7%)	57/ 666 (8.6%)	0.55 (0.36, 0.86)	0.1842
>=60 ml/min/1.73m2	176/ 2499 (7.0%)	221/ 2493 (8.9%)	0.77 (0.63, 0.94)	
eGFR (cut-offs: 15, 30 and 60 ml/min/1.73m2)				
<15 ml/min/1.73m2	0/ 2 (0.0%)	0/ 0		0.2093
15 - <30 ml/min/1.73m2	1/ 13 (7.7%)	1/ 28 (3.6%)	1.47 (0.09, 23.54)	
30 - <60 ml/min/1.73m2	30/ 646 (4.6%)	56/ 638 (8.8%)	0.53 (0.34, 0.83)	
>=60 ml/min/1.73m2	176/ 2499 (7.0%)	221/ 2493 (8.9%)	0.77 (0.63, 0.94)	
eGFR (cut-offs: 30, 50 and 80 ml/min/1.73m2)				
<30 ml/min/1.73m2	1/ 15 (6.7%)	1/ 28 (3.6%)	1.47 (0.09, 23.54)	0.1713
30 - 50 ml/min/1.73m2	14/ 343 (4.1%)	32/ 308 (10.4%)	0.39 (0.21, 0.73)	
>50 - 80 ml/min/1.73m2	80/ 1367 (5.9%)	106/ 1369 (7.7%)	0.76 (0.57, 1.02)	
>80 ml/min/1.73m2	112/ 1435 (7.8%)	139/ 1454 (9.6%)	0.78 (0.61, 1.00)	
Fragile subjects				
No	166/ 2338 (7.1%)	201/ 2332 (8.6%)	0.80 (0.65, 0.98)	0.1385
Yes	44/ 835 (5.3%)	78/ 839 (9.3%)	0.58 (0.40, 0.84)	
Prior coronary artery disease				
No	144/ 2233 (6.4%)	205/ 2263 (9.1%)	0.71 (0.57, 0.87)	0.4459
Yes	73/ 1052 (6.9%)	84/ 1015 (8.3%)	0.82 (0.60, 1.12)	




Riva. + ASA n/N(%)
Plac. + ASA n/N(%)
Hazard Ratio and 95% CI
HR (95% CI)
Inter. p-value (a)
Prior MI
No 181/ 2920 (6.2%) 265/ 2928 (9.1%) 0.68 (0.56, 0.82) 0.0104
Yes 36/ 365 (9.9%) 24/ 349 (6.9%) 1.40 (0.84, 2.36)
Prior MI and age <65 years
No 17/ 225 (7.6%) 17/ 229 (7.4%) 1.00 (0.51, 1.95) 0.1475
Yes 19/ 140 (13.6%) 7/ 120 (5.8%) 2.31 (0.96, 5.56)
Prior MI and eGFR < 60 mL/min
No 29/ 261 (11.1%) 15/ 225 (6.7%) 1.57 (0.84, 2.93) 0.3529
Yes 6/ 87 (6.9%) 8/ 103 (7.8%) 0.86 (0.30, 2.48)
Prior history of limb revascularization
No 123/ 2104 (5.8%) 156/ 2122 (7.4%) 0.80 (0.63, 1.01) 0.2844
Yes 94/ 1181 (8.0%) 133/ 1155 (11.5%) 0.66 (0.51, 0.86)
Carotid artery disease history
No 200/ 3002 (6.7%) 268/ 2982 (9.0%) 0.73 (0.61, 0.88) 0.6781
Yes 17/ 282 (6.0%) 21/ 293 (7.2%) 0.85 (0.45, 1.62)
History of heart failure
No 196/ 3017 (6.5%) 264/ 3005 (8.8%) 0.73 (0.61, 0.88) 0.6884
Yes 21/ 267 (7.9%) 25/ 272 (9.2%) 0.82 (0.46, 1.47)
Diabetes mellitus
No 120/ 1972 (6.1%) 186/ 1961 (9.5%) 0.64 (0.51, 0.80) 0.0432
Yes 97/ 1313 (7.4%) 103/ 1316 (7.8%) 0.92 (0.70, 1.22)
Smoking status
NEVER 24/ 662 (3.6%) 54/ 689 (7.8%) 0.47 (0.29, 0.76) 0.0762
FORMER 97/ 1475 (6.6%) 131/ 1456 (9.0%) 0.72 (0.55, 0.93)
CURRENT 96/ 1147 (8.4%) 104/ 1132 (9.2%) 0.89 (0.67, 1.17)
Hypertension
No 45/ 601 (7.5%) 57/ 620 (9.2%) 0.81 (0.55, 1.19) 0.6309
Yes 172/ 2684 (6.4%) 232/ 2658 (8.7%) 0.72 (0.59, 0.88)
Hyperlipidemia
No 99/ 1313 (7.5%) 134/ 1310 (10.2%) 0.74 (0.57, 0.96) 0.9651
Yes 118/ 1971 (6.0%) 155/ 1968 (7.9%) 0.75 (0.59, 0.95)
0.1
1
10
Favours Riva+ASA
Favours Plac+ASA

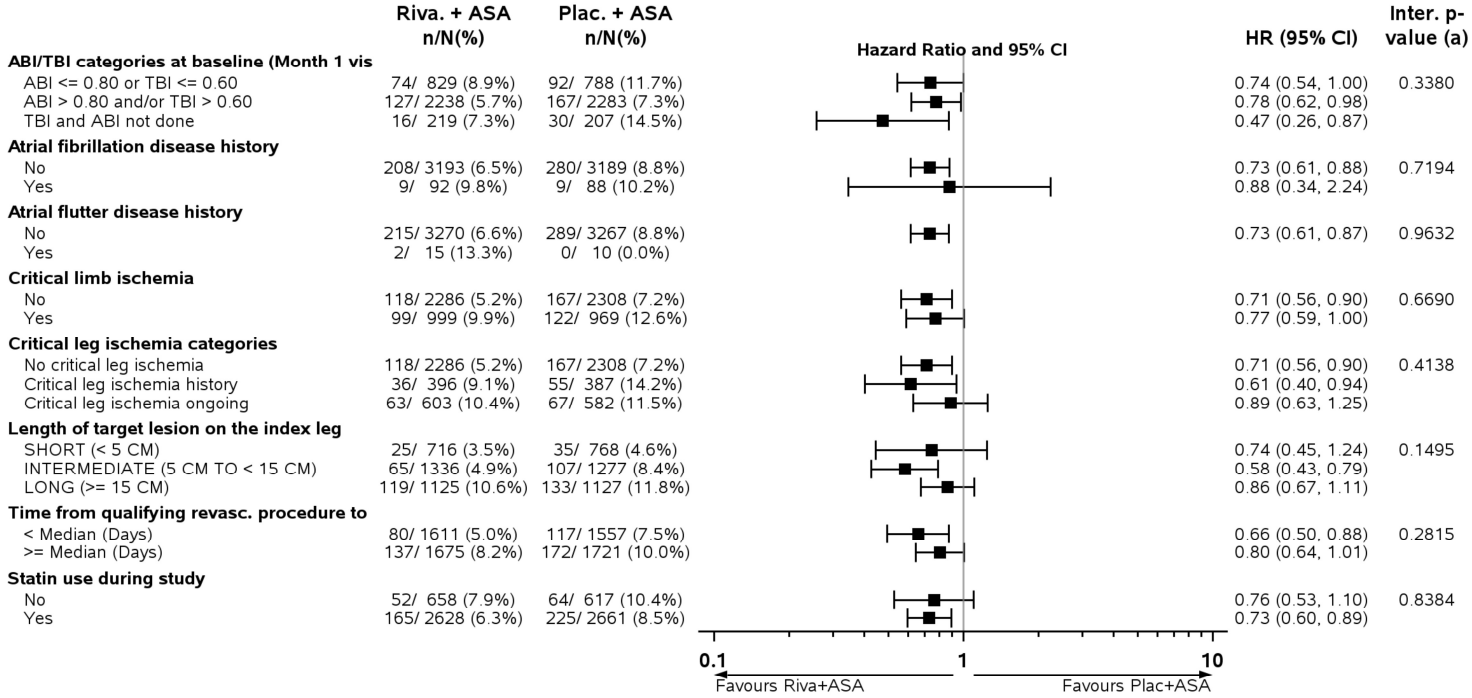


Figure displays outcome events meeting the definition as adjudicated by Independent Clinical Adjudication Committee (ICAC). Subgroup variables from Atrial fibrillation disease history and below are added post-hoc.
The ITT analysis set includes all randomized subjects. The ITT data scope includes outcome 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 Cox proportional hazards model stratified by type of procedure and clopidogrel use (per IxRS) (except for subgroups related to qualifying revascularization procedure or clopidogrel use), with treatment as the only covariate.
(a) P-value for interaction is based on the Cox proportional hazards model stratified by type of procedure and clopidogrel use (per IxRS) by adding the corresponding treatment interaction term.

Source: 5.3.5.1.1 PH-40164/Figure 14.2.5.1/6