**Table 3** Results for multivariable analysis for risk of bleeding in the rivaroxaban group

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | **Patients without bleed** | **Patients with bleed** | **Crude Odds Ratio (95% CI)** | **Adjusted Odds Ratio**ab **(95% CI)** |
| Patients, *N* | 68 | 29 |  |  |
|  |  |  |  |  |
| Class I peak plasma concentration, n (%) | 28 (41.2) | 8 (27.6) | Ref |  |
| Class II-IV peak plasma concentration, n (%) | 40 (58.8) | 21 (72.4) | 1.84 (0.71 – 4.74) |  |
|  |  |  |  |  |
| Class I trough plasma concentration, n (%) | 37 (54.4) | 17 (58.6) | Ref |  |
| Class II-IV trough plasma concentration, n (%) | 31 (45.6) | 12 (41.4) | 0.84 (0.35 – 2.03) |  |
|  |  |  |  |  |
| BMI (kg/m2), median (IQR) | 27.4 (24.4 – 31.2) | 25.1 (22.6 – 28.7) | 0.92 (0.84 – 1.01)\* | 0.91 (0.80 – 1.03) |
| CrCl (mL/min), median (IQR)c | 70.8 (57.7 – 85.8) | 61.5 (49.4 – 79.8) | 0.98 (0.96 – 1.00)\* | 0.99 (0.96 – 1.02) |
| Previous SSE, n (%) | 15 (22.1) | 2 (6.9) | 0.26 (0.06 – 1.23)\* | 0.25 (0.05 – 1.27)\* |
|  |  |  |  |  |
| No HMG-CoA reductase inhibitor, n (%) | 21 (30.9) | 6 (20.7) | Ref | Ref |
| Atorvastatin, n (%) | 43 (63.2) | 14 (48.3) | 1.14 (0.38 – 3.39) | 1.40 (0.41 – 4.73) |
| Rosuvastatin, n (%) | 0 (0.0) | 2 (6.9) | NAd | NAd |
| Simvastatin, n (%) | 4 (5.9) | 7 (24.1) | **6.13 (1.33 – 28.21)\*\*** | **6.14 (1.18 – 31.97)\*\*** |
| Abbreviations: *CI* confidence interval, *BMI* body mass index, *IQR* inter-quartile range, *CrCl* creatinine clearance, *SSE* stroke and systemic embolism, *HMG-CoA* 3-hydroxy-3-methylglutaryl coenzyme A.  \*\*p-value < 0.05.  \*p-value < 0.10.  a Adjusted for BMI, CrCl, previous SSE, concomitant use of atorvastatin, rosuvastatin or simvastatin.  b There were missing data for CrCl in the dataset. Multivariable regression was performed on available data (Without bleed: *N* = 66; With bleed: *N* = 28).  c There were missing data for this variable in the dataset. Median (IQR) for this variable is presented based on available data (Without bleed: *N* = 66; With bleed: *N* = 28).  d As the cell count for patients without bleed and with concomitant use of rosuvastatin is 0, the denominator of the odds ratio equation is 0 resulting in a very large odds ratio. | | | | |