Hemispheric Lateralization and Outcomes After ICH: A Pooled Analysis of Clinical Trials

Study Protocol and Statistical Analysis Plan

Nikhil Patel, MD

## Introduction

Patients with neurological injury experience different symptoms between the left and right hemispheres, and this may have.

## Methods

### Pooling RCTs

Randomized trials and observational studies included in the analysis:

* ATACH2
* ERICH
* MISTIE
* MISTIE III
* CLEAR-IVH

### Table 1

Note: Using an external vector in selections is ambiguous.  
i Use `all\_of(atachVarsTableOne)` instead of `atachVarsTableOne` to silence this message.  
i See <https://tidyselect.r-lib.org/reference/faq-external-vector.html>.  
This message is displayed once per session.

Stratified by ich.laterality  
 Left Right   
 n 475 519   
 age (mean (SD)) 61.82 (12.93) 62.17 (13.13)   
 sex = Male (%) 295 ( 62.1) 318 ( 61.3)   
 ethnicity (%)   
 Hispanic or Latino 43 ( 9.1) 35 ( 6.7)   
 Not Hispanic or Latino 423 ( 89.1) 464 ( 89.4)   
 Unknown/Not Reported 9 ( 1.9) 20 ( 3.9)   
 race (%)   
 American Indian or Alaska Native 2 ( 0.4) 2 ( 0.4)   
 Asian 265 ( 55.8) 295 ( 56.8)   
 Black or African-American 58 ( 12.2) 72 ( 13.9)   
 Other/Not Reported 7 ( 1.5) 9 ( 1.7)   
 White 143 ( 30.1) 141 ( 27.2)   
 enrolling.country (%)   
 China 56 ( 11.8) 79 ( 15.2)   
 Germany 20 ( 4.2) 19 ( 3.7)   
 Japan 148 ( 31.2) 141 ( 27.2)   
 South Korea 10 ( 2.1) 7 ( 1.3)   
 Taiwan 38 ( 8.0) 56 ( 10.8)   
 United States 203 ( 42.7) 217 ( 41.8)   
 stroke (%)   
 NA 3 ( 0.6) 3 ( 0.6)   
 No 402 ( 84.6) 422 ( 81.3)   
 Yes 70 ( 14.7) 94 ( 18.1)   
 cad (%)   
 NA 5 ( 1.1) 3 ( 0.6)   
 No 469 ( 98.7) 516 ( 99.4)   
 Yes 1 ( 0.2) 0 ( 0.0)   
 chf (%)   
 NA 7 ( 1.5) 3 ( 0.6)   
 No 454 ( 95.6) 493 ( 95.0)   
 Yes 14 ( 2.9) 23 ( 4.4)   
 afib (%)   
 NA 5 ( 1.1) 5 ( 1.0)   
 No 458 ( 96.4) 490 ( 94.4)   
 Yes 12 ( 2.5) 24 ( 4.6)   
 pvd (%)   
 NA 4 ( 0.8) 7 ( 1.3)   
 No 459 ( 96.6) 502 ( 96.7)   
 Yes 12 ( 2.5) 10 ( 1.9)   
 hld (%)   
 NA 25 ( 5.3) 32 ( 6.2)   
 No 337 ( 70.9) 359 ( 69.2)   
 Yes 113 ( 23.8) 128 ( 24.7)   
 dm2 (%)   
 NA 8 ( 1.7) 10 ( 1.9)   
 No 382 ( 80.4) 418 ( 80.5)   
 Yes 85 ( 17.9) 91 ( 17.5)   
 tobacco = Yes (%) 123 (100.0) 140 (100.0)   
 symptom.onset (mean (SD)) -182.38 (55.83) -184.41 (58.16)   
 sbp.initial (mean (SD)) 200.76 (26.59) 200.58 (27.30)   
 dbp.initial (mean (SD)) 111.82 (20.68) 110.22 (20.59)   
 gcs.baseline (mean (SD)) 13.13 (2.40) 14.22 (1.59)   
 nihss.baseline (mean (SD)) 12.50 (7.85) 10.88 (5.75)   
 ich.location.baseline (%)   
 Basal Ganglia 263 ( 55.4) 246 ( 47.4)   
 Lobar 55 ( 11.6) 54 ( 10.4)   
 Thalamus 157 ( 33.1) 219 ( 42.2)   
 ivh = Yes (%) 124 ( 26.1) 137 ( 26.4)   
 hydrocephalus = Yes (%) 57 ( 12.0) 76 ( 14.6)   
 ich.volume.cc (mean (SD)) 13.67 (12.24) 13.81 (12.06)   
 ivh.volume.cc (mean (SD)) 2.30 (6.49) 2.37 (6.30)   
 phe.volume.cc (mean (SD)) 2.10 (2.36) 2.05 (2.74)   
 sp.shift.baseline (mean (SD)) 1.06 (1.77) 1.35 (1.83)   
 mech.ventilation = Yes (%) 59 ( 12.5) 76 ( 14.8)   
 intubation.days (mean (SD)) 8.46 (7.27) 6.68 (4.73)   
 extubation.date (mean (SD)) 9.35 (7.69) 7.40 (5.31)   
 trach = Yes (%) 19 ( 32.2) 19 ( 25.0)   
 trach.date (mean (SD)) 12.21 (5.85) 6.79 (4.53)   
 evd = Yes (%) 31 ( 6.6) 38 ( 7.4)   
 evd.days (mean (SD)) 11.61 (12.28) 8.87 (5.82)   
 nsgy.evacuation = Yes (%) 13 ( 2.8) 30 ( 5.8)   
 nsgy.evacuation.date (mean (SD)) 0.69 (0.85) 2.00 (4.34)   
 mrs30 (mean (SD)) 3.05 (1.39) 3.17 (1.44)   
 mrs90 (mean (SD)) 2.52 (1.36) 2.64 (1.41)   
 euro.mobility (%)   
 No Problems 147 ( 34.7) 148 ( 32.7)   
 Some Problems 246 ( 58.0) 243 ( 53.8)   
 Confined to Bed 31 ( 7.3) 61 ( 13.5)   
 euro.selfcare (%)   
 No Problems 213 ( 50.2) 195 ( 43.1)   
 Some Problems 150 ( 35.4) 162 ( 35.8)   
 Unable to Wash or Dress Myself 61 ( 14.4) 95 ( 21.0)   
 euro.usual (%)   
 No Problems 116 ( 27.4) 128 ( 28.3)   
 Some Problems 203 ( 47.9) 200 ( 44.2)   
 Unable to Perform My Usual Activities 105 ( 24.8) 124 ( 27.4)   
 euro.pain (%)   
 No Pain/Discomfort 234 ( 55.2) 224 ( 49.7)   
 Some Moderate Pain/Discomfort 183 ( 43.2) 212 ( 47.0)   
 Extreme Pain/Discomfort 7 ( 1.7) 15 ( 3.3)   
 euro.anxiety (%)   
 Not Anxious/Depressed 260 ( 61.5) 272 ( 60.3)   
 Moderately Anxious/Depressed 148 ( 35.0) 161 ( 35.7)   
 Extremely Anxious/Depressed 15 ( 3.5) 18 ( 4.0)   
 euro.vas (mean (SD)) 64.93 (21.29) 65.11 (21.51)   
 EQ\_INDEX (mean (SD)) 0.69 (0.24) 0.65 (0.28)   
 ich.laterality = Right (%) 0 ( 0.0) 519 (100.0)   
 Stratified by ich.laterality  
 p test  
 n   
 age (mean (SD)) 0.672   
 sex = Male (%) 0.838   
 ethnicity (%) 0.084   
 Hispanic or Latino   
 Not Hispanic or Latino   
 Unknown/Not Reported   
 race (%) 0.838   
 American Indian or Alaska Native   
 Asian   
 Black or African-American   
 Other/Not Reported   
 White   
 enrolling.country (%) 0.250   
 China   
 Germany   
 Japan   
 South Korea   
 Taiwan   
 United States   
 stroke (%) 0.358   
 NA   
 No   
 Yes   
 cad (%) 0.407   
 NA   
 No   
 Yes   
 chf (%) 0.178   
 NA   
 No   
 Yes   
 afib (%) 0.208   
 NA   
 No   
 Yes   
 pvd (%) 0.613   
 NA   
 No   
 Yes   
 hld (%) 0.763   
 NA   
 No   
 Yes   
 dm2 (%) 0.952   
 NA   
 No   
 Yes   
 tobacco = Yes (%) NA   
 symptom.onset (mean (SD)) 0.574   
 sbp.initial (mean (SD)) 0.917   
 dbp.initial (mean (SD)) 0.223   
 gcs.baseline (mean (SD)) <0.001   
 nihss.baseline (mean (SD)) <0.001   
 ich.location.baseline (%) 0.012   
 Basal Ganglia   
 Lobar   
 Thalamus   
 ivh = Yes (%) 0.974   
 hydrocephalus = Yes (%) 0.259   
 ich.volume.cc (mean (SD)) 0.857   
 ivh.volume.cc (mean (SD)) 0.860   
 phe.volume.cc (mean (SD)) 0.732   
 sp.shift.baseline (mean (SD)) 0.010   
 mech.ventilation = Yes (%) 0.355   
 intubation.days (mean (SD)) 0.089   
 extubation.date (mean (SD)) 0.087   
 trach = Yes (%) 0.465   
 trach.date (mean (SD)) 0.003   
 evd = Yes (%) 0.715   
 evd.days (mean (SD)) 0.226   
 nsgy.evacuation = Yes (%) 0.028   
 nsgy.evacuation.date (mean (SD)) 0.291   
 mrs30 (mean (SD)) 0.179   
 mrs90 (mean (SD)) 0.207   
 euro.mobility (%) 0.012   
 No Problems   
 Some Problems   
 Confined to Bed   
 euro.selfcare (%) 0.020   
 No Problems   
 Some Problems   
 Unable to Wash or Dress Myself   
 euro.usual (%) 0.523   
 No Problems   
 Some Problems   
 Unable to Perform My Usual Activities   
 euro.pain (%) 0.109   
 No Pain/Discomfort   
 Some Moderate Pain/Discomfort   
 Extreme Pain/Discomfort   
 euro.anxiety (%) 0.908   
 Not Anxious/Depressed   
 Moderately Anxious/Depressed   
 Extremely Anxious/Depressed   
 euro.vas (mean (SD)) 0.915   
 EQ\_INDEX (mean (SD)) 0.011   
 ich.laterality = Right (%) <0.001