623 Assignment 4

Background

Randomization (randomized controlled trial) - 14 days after randomization or prior discharge and at 6 months. Total of 19435 patients with acute stroke, 99% complete follow-up. 26.4% aged over 80, background stroke care was limited and non of the patients received thrombolytic therapy.

Questions

What are the characteristics of the patient groups (aspirin and high heparin)?

Data Resource and Approach

Used version 2 corrected IST dataset, which includes data on 19 435 patients with acute stroke, with 99% complete follow-up. Over 26.4% patients were aged over 80 years at study entry. Background stroke care was limited and none of the patients received thrombolytic therapy. Based on the variables selection, following features are used in to discuss the characteristics of the aspirin and high heparin patient groups. Sysmptons noted on waking - RSLEEP, CT before randomisation - RCT, Conscious State - RCONSC, Age - AGE, Gender - SEX, Blood pressure - RSBP, Aspirin given for 14 days or till death or discharge - DASP14, Indicator of any stroke within 14 days - STR14, Medium dose heparin given for 14 days or till death/discharge (Y/N) - DMH14, HTI14, PE14, DVT14, TRAN14.

In this study, data is first be selected and categorized into age groups before being divided into subsets based on the number of patients who received either aspirin or high-dose heparin within 14 days from the start of the study. Age group are separated for each ten years, started from the 20 years old, such as 20 years to 30 years categorized as 2. Records of patients who have been treated with both treatments or only one of them will be excluded from each subset. Subsequently, we will examine patients diagnosed with a stroke within 14 days and those who were not diagnosed within this timeframe to analyze the outcomes. Descriptive data for each group of participants will be assessed separately to ensure a thorough evaluation. Character data is converted into numerical data to provide more descriptive information.

Result

| • • | RStudio: Notebook Output | | | | | | | | |
|-------------------|--------------------------|-------------------|-------------------|-------------------|-------------------|-------------------|-------------------|-------------------|---------------------|
| | 2 (N=14) | 3 (N=64) | 4 (N=254) | 5 (N=700) | 6 (N=1643) | 7 (N=2449) | 8 (N=1785) | 9 (N=184) | Overall (N=7093) |
| SEX | (, | (11 01) | (11 =0 1) | (11 100) | (11 1010) | (11 = 1110) | (11 1100) | (11 10 1) | (11 / 555) |
| F | 8 (57.1%) | 34 (53.1%) | 79 (31.1%) | 209 (29.9%) | 606 (36.9%) | 1168 (47.7%) | 1084 (60.7%) | 140 (76.1%) | 3328 (46.9%) |
| M | 6 (42.9%) | 30 (46.9%) | 175 (68.9%) | 491 (70.1%) | 1037 (63.1%) | 1281 (52.3%) | 701 (39.3%) | 44 (23.9%) | 3765 (53.1%) |
| AGE | , , | , , | , , | , , | , , | , , | , , | , , | , , |
| Mean (SD) | 25.9 (2.70) | 35.4 (3.00) | 45.6 (2.84) | 55.2 (2.86) | 65.1 (2.78) | 74.5 (2.77) | 83.6 (2.70) | 91.8 (2.00) | 71.7 (11.6) |
| Median [Min, Max] | 26.5 [20.0, 29.0] | 36.0 [30.0, 39.0] | 46.0 [40.0, 49.0] | 56.0 [50.0, 59.0] | 65.0 [60.0, 69.0] | 74.0 [70.0, 79.0] | 83.0 [80.0, 89.0] | 91.0 [90.0, 98.0] | 73.0 [20.0, 98.0 |
| RSLEEP | | | | | | | | | |
| N | 10 (71.4%) | 48 (75.0%) | 165 (65.0%) | 490 (70.0%) | 1162 (70.7%) | 1746 (71.3%) | 1240 (69.5%) | 136 (73.9%) | 4997 (70.4%) |
| Υ | 4 (28.6%) | 16 (25.0%) | 89 (35.0%) | 210 (30.0%) | 481 (29.3%) | 703 (28.7%) | 545 (30.5%) | 48 (26.1%) | 2096 (29.6%) |
| RCONSC | | | | | | | | | |
| D | 2 (14.3%) | 12 (18.8%) | 42 (16.5%) | 108 (15.4%) | 274 (16.7%) | 525 (21.4%) | 483 (27.1%) | 76 (41.3%) | 1522 (21.5%) |
| F | 11 (78.6%) | 51 (79.7%) | 211 (83.1%) | 588 (84.0%) | 1354 (82.4%) | 1891 (77.2%) | 1263 (70.8%) | 104 (56.5%) | 5473 (77.2%) |
| U | 1 (7.1%) | 1 (1.6%) | 1 (0.4%) | 4 (0.6%) | 15 (0.9%) | 33 (1.3%) | 39 (2.2%) | 4 (2.2%) | 98 (1.4%) |
| RCT | | | | | | | | | |
| N | 1 (7.1%) | 3 (4.7%) | 50 (19.7%) | 149 (21.3%) | 488 (29.7%) | 811 (33.1%) | 684 (38.3%) | 87 (47.3%) | 2273 (32.0%) |
| Υ | 13 (92.9%) | 61 (95.3%) | 204 (80.3%) | 551 (78.7%) | 1155 (70.3%) | 1638 (66.9%) | 1101 (61.7%) | 97 (52.7%) | 4820 (68.0%) |
| RSBP | | | | | | | | | |
| Mean (SD) | 141 (27.7) | 140 (27.9) | 147 (24.4) | 156 (27.4) | 161 (27.1) | 162 (27.4) | 162 (27.8) | 158 (28.9) | 160 (27.6) |
| Median [Min, Max] | 130 [100, 185] | 139 [90.0, 230] | 140 [100, 220] | 150 [90.0, 250] | 160 [90.0, 280] | 160 [70.0, 280] | 160 [90.0, 284] | 160 [90.0, 280] | 160 [70.0, 284] |
| STRK14 | | | | | | | | | |
| No | 14 (100%) | 64 (100%) | 254 (100%) | 676 (96.6%) | 1596 (97.1%) | 2383 (97.3%) | 1720 (96.4%) | 179 (97.3%) | 6886 (97.1%) |
| Yes | 0 (0%) | 0 (0%) | 0 (0%) | 24 (3.4%) | 47 (2.9%) | 66 (2.7%) | 65 (3.6%) | 5 (2.7%) | 207 (2.9%) |
| HTI14 | | | | | | | | | |
| No | 14 (100%) | 64 (100%) | 254 (100%) | 699 (99.9%) | 1639 (99.8%) | 2447 (99.9%) | 1784 (99.9%) | 184 (100%) | 7085 (99.9%) |
| Yes | 0 (0%) | 0 (0%) | 0 (0%) | 1 (0.1%) | 4 (0.2%) | 2 (0.1%) | 1 (0.1%) | 0 (0%) | 8 (0.1%) |
| PE14 | | | | | | | | | |
| No | 14 (100%) | 64 (100%) | 254 (100%) | 699 (99.9%) | 1633 (99.4%) | 2431 (99.3%) | 1775 (99.4%) | 183 (99.5%) | 7053 (99.4%) |
| Yes | 0 (0%) | 0 (0%) | 0 (0%) | 1 (0.1%) | 10 (0.6%) | 18 (0.7%) | 10 (0.6%) | 1 (0.5%) | 40 (0.6%) |
| DVT14 | | | | | | | | | |
| No | 14 (100%) | 64 (100%) | 254 (100%) | 700 (100%) | 1643 (100%) | 2446 (99.9%) | 1782 (99.8%) | 184 (100%) | 7087 (99.9%) |
| Yes | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 3 (0.1%) | 3 (0.2%) | 0 (0%) | 6 (0.1%) |
| TRAN14 | | | | | | | | | |
| No | 14 (100%) | 64 (100%) | 254 (100%) | 700 (100%) | 1637 (99.6%) | 2436 (99.5%) | 1774 (99.4%) | 181 (98.4%) | 7060 (99.5%) |
| Yes | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 6 (0.4%) | 13 (0.5%) | 11 (0.6%) | 3 (1.6%) | 33 (0.5%) |
| Group | | | | | | | | | |
| Asprin | 14 (100%) | 64 (100%) | 254 (100%) | 700 (100%) | 1643 (100%) | 2449 (100%) | 1785 (100%) | 184 (100%) | 7093 (100%) |

Figure 1: Patients Received Asprin within 14 Days

Discussion

Most patients who received aspirin within 14 days are located in age groups 6, 7, and 8, indicating that the majority of these patients are within the age range of 60 to 89 years. The mean age for all patients who received aspirin within 14 days is 71.7 years. Overall, 70.4% of patients did not have any symptoms noted upon waking. In total, 77.2% of patients were conscious at randomization, with over 80% of patients in age groups 4, 5, and 6 being fully alert at randomization. The prevalence of having a CT scan before randomization decreases as age increases, except for age groups 2 and 3, where age group 3 has a slightly higher prevalence, with a difference of less than 3%. Starting from age group 5, the prevalence of any stroke indicator within 14 days increases with age, except in age group 9, which may be due to the smaller population of patients older than 90 years compared to age groups 7 and 8. The indicator of hemorrhagic transformation within 14 days only appears from age group 5 to age group 8. The indicator of pulmonary embolism within 14 days appears similarly from age group 5 to age group 9. Only six patients have an indicator of deep vein thrombosis on their discharge form. The prevalence of the indicator of major non-cerebral bleeding within 14 days in age group 9 is at least 2.5 times higher than other age groups that recorded positive TRAN14 results.

| • • | RStudio: Notebook Output | | | | | | | | |
|-------------------|--------------------------|-------------------|---|-------------------|---|---|-------------------|---|---------------------|
| | 2 (N=3) | 3 (N=18) | 4 (N=60) | 5 (N=222) | 6 (N=491) | 7 (N=731) | 8 (N=550) | 9 (N=42) | Overall (N=2117) |
| SEX | , , , | (| (************************************** | , , , | (************************************** | (************************************** | (| (************************************** | (, |
| F | 2 (66.7%) | 8 (44.4%) | 25 (41.7%) | 60 (27.0%) | 162 (33.0%) | 350 (47.9%) | 316 (57.5%) | 31 (73.8%) | 954 (45.1%) |
| M | 1 (33.3%) | 10 (55.6%) | 35 (58.3%) | 162 (73.0%) | 329 (67.0%) | 381 (52.1%) | 234 (42.5%) | 11 (26.2%) | 1163 (54.9%) |
| AGE | | | | | | | | | |
| Mean (SD) | 26.7 (2.08) | 35.7 (2.54) | 46.0 (2.96) | 55.4 (2.87) | 65.3 (2.89) | 74.6 (2.71) | 83.5 (2.63) | 91.7 (2.02) | 71.9 (11.2) |
| Median [Min, Max] | 26.0 [25.0, 29.0] | 35.5 [31.0, 39.0] | 47.0 [40.0, 49.0] | 56.0 [50.0, 59.0] | 66.0 [60.0, 69.0] | 74.0 [70.0, 79.0] | 83.0 [80.0, 89.0] | 91.0 [90.0, 98.0] | 73.0 [25.0, 98.0 |
| N | 2 (66.7%) | 13 (72.2%) | 46 (76.7%) | 144 (64.9%) | 332 (67.6%) | 529 (72.4%) | 391 (71.1%) | 29 (69.0%) | 1486 (70.2%) |
| Υ | 1 (33.3%) | 5 (27.8%) | 14 (23.3%) | 78 (35.1%) | 159 (32.4%) | 202 (27.6%) | 159 (28.9%) | 13 (31.0%) | 631 (29.8%) |
| RCONSC | | , , | . / | . , | . , | | | . / | , |
| D | 2 (66.7%) | 1 (5.6%) | 12 (20.0%) | 33 (14.9%) | 91 (18.5%) | 174 (23.8%) | 149 (27.1%) | 17 (40.5%) | 479 (22.6%) |
| F | 1 (33.3%) | 15 (83.3%) | 48 (80.0%) | 188 (84.7%) | 395 (80.4%) | 550 (75.2%) | 384 (69.8%) | 23 (54.8%) | 1604 (75.8%) |
| U | 0 (0%) | 2 (11.1%) | 0 (0%) | 1 (0.5%) | 5 (1.0%) | 7 (1.0%) | 17 (3.1%) | 2 (4.8%) | 34 (1.6%) |
| RCT | | | | | | | | | |
| Υ | 3 (100%) | 16 (88.9%) | 52 (86.7%) | 182 (82.0%) | 353 (71.9%) | 491 (67.2%) | 337 (61.3%) | 23 (54.8%) | 1457 (68.8%) |
| N | 0 (0%) | 2 (11.1%) | 8 (13.3%) | 40 (18.0%) | 138 (28.1%) | 240 (32.8%) | 213 (38.7%) | 19 (45.2%) | 660 (31.2%) |
| RSBP | | | | | | | | | |
| Mean (SD) | 142 (29.3) | 138 (22.4) | 155 (34.1) | 156 (25.8) | 159 (25.7) | 162 (26.2) | 162 (26.8) | 158 (31.9) | 160 (26.7) |
| Median [Min, Max] | 130 [120, 175] | 131 [110, 180] | 150 [100, 250] | 150 [98.0, 230] | 160 [95.0, 250] | 160 [80.0, 244] | 160 [93.0, 247] | 160 [100, 240] | 160 [80.0, 250] |
| STRK14 | | | | | | | | | |
| No | 3 (100%) | 16 (88.9%) | 59 (98.3%) | 213 (95.9%) | 478 (97.4%) | 685 (93.7%) | 526 (95.6%) | 39 (92.9%) | 2019 (95.4%) |
| Yes | 0 (0%) | 2 (11.1%) | 1 (1.7%) | 9 (4.1%) | 13 (2.6%) | 46 (6.3%) | 24 (4.4%) | 3 (7.1%) | 98 (4.6%) |
| HTI14 | | | | | | | | | |
| No | 3 (100%) | 18 (100%) | 60 (100%) | 222 (100%) | 490 (99.8%) | 727 (99.5%) | 547 (99.5%) | 42 (100%) | 2109 (99.6%) |
| Yes | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 1 (0.2%) | 4 (0.5%) | 3 (0.5%) | 0 (0%) | 8 (0.4%) |
| PE14 | | | | | | | | | |
| No | 3 (100%) | 18 (100%) | 60 (100%) | 222 (100%) | 485 (98.8%) | 727 (99.5%) | 549 (99.8%) | 42 (100%) | 2106 (99.5%) |
| Yes | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 6 (1.2%) | 4 (0.5%) | 1 (0.2%) | 0 (0%) | 11 (0.5%) |
| DVT14 | | | | | | | | | |
| No | 3 (100%) | 18 (100%) | 60 (100%) | 222 (100%) | 491 (100%) | 731 (100%) | 549 (99.8%) | 42 (100%) | 2116 (100.0%) |
| Yes | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 1 (0.2%) | 0 (0%) | 1 (0.0%) |
| TRAN14 | | | | | | | | | |
| No | 3 (100%) | 18 (100%) | 60 (100%) | 222 (100%) | 484 (98.6%) | 725 (99.2%) | 542 (98.5%) | 42 (100%) | 2096 (99.0%) |
| Yes | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 7 (1.4%) | 6 (0.8%) | 8 (1.5%) | 0 (0%) | 21 (1.0%) |
| Group | | | | | | | | | |
| High_Deparin | 3 (100%) | 18 (100%) | 60 (100%) | 222 (100%) | 491 (100%) | 731 (100%) | 550 (100%) | 42 (100%) | 2117 (100%) |

Figure 2: Patients Received High-deparin within 14 Days

Discussion

Most patients who received high-dose heparin within 14 days are located in age groups 5, 6, 7, and 8, indicating that the majority of these patients are within the age range of 50 to 89 years. The mean age for all patients who received high-dose heparin within 14 days is 71.9 years. Overall, 70.2% of patients did not have any symptoms noted upon waking. In total, 75.8% of patients were conscious at randomization, with over 80% of patients in age groups 3, 4, 5, and 6 being fully alert at randomization. The prevalence of having a CT scan before randomization decreases as age increases. Starting from age group 3, the prevalence of any stroke indicator within 14 days appears in different age groups, but there are no notable trends associated with increasing ages. The indicators of hemorrhagic transformation within 14 days and pulmonary embolism within 14 days only appear from age group 6 to age group 8. Only one patient has an indicator of deep vein thrombosis on their discharge form. The prevalence of the indicator of major non-cerebral bleeding within 14 days in age groups 6 and 8 is over 1%, while it is less than 1% in age group 7.

Reference

Sandercock, Peter, et al. International Stroke Trial Database (Version 2). 2 Nov. 2011. datashare.ed.ac.uk, https://doi.org/10.7488/ds/104.

User Guide: How to Create Tables of Baseline Characteristics (Descriptive Statistics). https://certara.github.io/table1c/vignettes/table1c-howto.html.

Zhang, Yilong, et al. Chapter 4 Baseline Characteristics | R for Clinical Study Reports and Submission. r4csr.org, https://r4csr.org/baseline-characteristics.html.

Abstract Plan

- Survival Rate between two groups (Aspirin and high heparin)
- OCCODE six month outcome
- Outcome final diagnosis

Background:

Current literatures found aspirin reduced the risk of recurrent ischemic stroke by approximately 60% within 6 weeks, with the greatest benefit seen in patients presenting with TIA or minor stroke. (Rothwell, Peter M, 2016) and a significantly higher mortality rate among stroke patients who were on clopidogrel than those on aspirin was noted in 12-month follow-up (Chi, Nai-Fang, 2018).

Objective: question: survival rate of patients who have been assign with aspirin, low dose heparin or high heparin in stroke trial. How does effcatcay distinct in different types of strokes? Methods: The IST dataset includes data on 19 435 patients with acute stroke, with 99% complete follow-up. Over 26.4% patients were aged over 80 years at study entry. Background stroke care was limited and none of the patients received thrombolytic therapy. Results: the result willI look at baseline and charactistices of patients who have received asprin or deparin within 14 days, and the survival rate after 6 months, also discover the cause of death for each subtype of stroke

Conclusion: limitation of this study, The study uses data from the IST dataset, which includes patients with acute stroke who did not receive thrombolytic therapy. This may limit the generalizability of the findings to other patient populations who may receive different treatments. The demographic might have different impact on the effetacy of medication

References:

Chi, Nai-Fang, et al. "Comparison Between Aspirin and Clopidogrel in Secondary Stroke Prevention Based on Real-World Data." Journal of the American Heart Association: Cardiovascular and Cerebrovascular Disease, vol. 7, no. 19, Sept. 2018, p. e009856. PubMed Central, https://doi.org/10.1161/JAHA.118.009856.

Rothwell, Peter M., et al. "Effects of Aspirin on Risk and Severity of Early Recurrent Stroke after Transient Ischaemic Attack and Ischaemic Stroke: Time-Course Analysis of Randomised Trials." Lancet (London, England), vol. 388, no. 10042, July 2016, pp. 365–75. PubMed Central, https://doi.org/10.1016/S0140-6736(16)30468-8.

Steen, Wouter van der, et al. "Safety and Efficacy of Aspirin, Unfractionated Heparin, Both, or Neither during Endovascular Stroke Treatment (MR CLEAN-MED): An Open-Label, Multicentre, Randomised Controlled Trial." The Lancet, vol. 399, no. 10329, Mar. 2022, pp. 1059–69. www.thelancet.com, https://doi.org/10.1016/S0140-6736(22)00014-9.