Intracranial atherosclerotic disease (ICAD) is the cause of ischemic stroke in 40% of Asians, 29% of African-Americans, and 10% of Caucasians, making it the most common cause of stroke in the world. A primary goal of stroke treatment is to prevent recurrence. In cohorts with real-world standard-of-care secondary prevention, the rate of recurrent ICAD stroke is high: over 20% of patients at 30 days from the initial stroke. The average annual rate of recurrence is 5% for all causes of stroke over the period 2000–2010. For patients with treated carotid atherosclerosis who have excellent medical and surgical options, the rate is less than 5%. This is the result of numerous major clinical trials aimed at improving secondary prevention in patients with cervical carotid atherosclerosis. In contrast, there have been only two major clinical trials for ICAD patients: WASID and SAMMPRIS. The WASID trial reported that ICAD patients with 50–99% stenosis had a 15% annual stroke recurrence with medical management. The SAMMPRIS trial included ICAD patients with 70–99% stenosis. This trial reported that treatment with aggressive medical management (including a wellness coach) was associated with a 15% annual recurrence rate compared to a 20% rate among patients who underwent an endovascular stenting procedure plus aggressive medical management. The high rates of stroke recurrence in these two trials with maximum medical management indicate that there is an urgent need for better stroke prevention regimens in this high-risk population.

The same treatments that dramatically reduce the risk of stroke for patients with cervical carotid atherosclerosis do not work well enough for ICAD. We therefore need to look at new approaches for stroke prevention in ICAD patients. The most promising sources of residual risk to mitigate include thrombosis, inflammation, and lipids. We want to develop innovative clinical trials that will test promising and safe drug regimens that mitigate these sources of residual risk for secondary stroke prevention in patients with ICAD. Through these trials, we aim to make necessary progress in the fight against ICAD—the most treatment-resistant and common form of ischemic stroke in the world.

Questions:
1. Should we include a standard of care arm?
2. What is an ideal endpoint for the platform phase 2?
3. How does one estimate the required number of patients per arm?
4. How does one efficiently pick winners?
5. Do you test arms in pairs (Wimbledon) or all simultaneous (Primaries)?
6. How many arms can one reasonably test simultaneously?

7. How do you determine your optimal cocktail most efficiently?

8. Is it conceivable to have a seamless multi-arm phase 2/3 design?

9. Is Bayesian or frequentist approach preferred?

Zoom Meeting Information

Topic: Workshop: Data Studio
Time: Apr 22, 2020 13:30 Pacific Time (US and Canada)
Meeting ID: 117 836 868

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