Is this patient appropriate for the CREST 2 Surigical equipoise

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Disclosures
Non relevant to this discussion

63 year old man referred October 2015 with left ICA stenosis, a Right thalamic CVA August 2015 resulting in mild left lower extremity weakness, now resolved. He denies residual weakness or any motor or sensory changes

Medication:
Atorvastatin
metformin
indomethacin
Lisinopril
aspirin

HGBA1C = 6.3%
eGFR > 60 ml/min
Total cholesterol 171 mg/dl
LDL 107 mg/dl
HDL 39 mg/dl

TTE – no evidence of patent foramen ovale bubble study

BP 128/75 HR 83 Wt 221 lbs Ht 69 inches

CN 2-12 intact
Carotids 2/2
Pulse exam
Femoral popliteal DP PT
R 2 2 0 0
L 2 2 0 0
Who would treat this patient?

Who would leave it to chance and enroll him in an asymptomatic carotid trial?

Overwhelming twitter response all unanimously voted to treat!

To be in equipoise between two treatments A and B is to be cognitively indifferent between statement, A is strictly more effective than B, and its negation. Equipoise regarding A and B is necessary for randomized assignment to treatments A and B to be beneficent and non-maleficient.

Mathematically equipoise has been held to require that the prior probability for either treatment A or treatment B being superior to the other is 0.5. It is therefore a state of uncertainty.

Contamination of bias

These results violate clinical equipoise and suggest the introduction of bias.
1. RCTs in 2011 and identified 319 studies testing an experimental therapy against a competitor.
2. 57% had an industry sponsor
3. 238,386 subjects out of 289,718 (82.3%) subjects studied
4. INDUSTRY SPONSORSHIP, OR of favorable result 2.8 95% CI 1.6-4.7, P<.0001
5. NON-INFERIORITY TRIAL DESIGN, OR of favorable result was 3.2 95% CI 1.5-6.6, P<.0002

Ethical grounds for not enrolling,
1. clinical intuition
2. guinea pigs.
3. Do not admit to uncertainty and ignorance
Result, Eligible patients do not get enrolled. This introduces issues of generalizability and reduced statistical power, eg., CREST 1.

Can we accept inconsistency among our peers (theoretical equipoise) as a substitute to your clinical intuition (clinical equipoise)?

Do we believe that the controlled experiment of a trial is more ethical than the uncontrolled experiment of routine?