CREST-2 May Change Little or Nothing in Carotid Treatment Practice. Why is This So?

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CREST-2
(>70% ASC > 6 months, Average-CEA Risk; Recruitment 2014-20)

1240 CEA vs MT
1240 CAS vs MT

Stroke or death within 44 days of randomization & ipsilateral stroke thereafter up to 4 years

7 Reasons Why CREST-2 May Change Little or Nothing—ie, Widespread, harmful & wasteful procedures for ACS continue…

1. CREST-2 has Changed Nothing Yet
If there is uncertainty or concern, where is the moratorium?

2. CREST-2 is Used to Show ‘Non-Inferiority’
But this is not enough—A new treatment must be better than others to justify investment in it.
3. CREST-2 is Underpowered to Rule Out Clinically Significant Differences

Like so many trials of CAS vs CEA which have then been used inappropriately to encourage more CAS…

BEAWRE: A non-significance difference statistically (underpowering) does not mean a non-significant difference clinically…

4. CREST-2 Studies ‘Average-Risk’ ACS

So doctors still think they can identify the high ipsilateral-stroke risk patients who benefit from their procedure:

i. 80-99% stenosis (25% of ACS patients over 4 years)

ii. Asymptomatic progression (20% of ACS patients)

iii. Echolucent plaque (30% of ACS patients)

iv. Ulcerated/rough surface plaque (86% of ACS patients)

v. Transcranial embolic signals (12-40% ACS patients)


5. CREST-2 Includes ‘Remotely’ Symptomatic Patients & Results Applied to Truly Asymptomatic Patients (Exaggerating any Procedural Benefit)

It may take 2-3 years for the ipsilateral stroke rate of SCS to fall to that of ACS

NASCET, Barnett et al 1998

Abbott et al 2007

No Wonder They are Under-Powered: Only About 2.5% of ACS Patients Will Have Stroke Caused by the Lesion During Life!

- Average annual ipsilateral stroke rate is 0.5%.
- We can probably do better
- About half the strokes occurring in the distribution of a ACS not are due to the lesion.
- Average age of diagnosing 50%-99% ACS: 70 yrs
- Average survival is 10 years (0.25 x 10 = 2.5%)
- Assume 30-day procedural stroke/death rate=0

6. Doctors are Still Paid to Do Un-necessary or Harmful Procedures

7. Patients Still Want a “Quick fix”

CREST-2 May Change Little or Nothing: Unnecessary/Harmful Procedures Continue
Time for a Rethink at Multiple Levels…

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