Is there a chance that ACST II can change the game?

Carlo Setacci

Vascular and Endovascular Surgery
University of Siena - Italy

Disclosure

Speaker name:

...Carlo Setacci.....

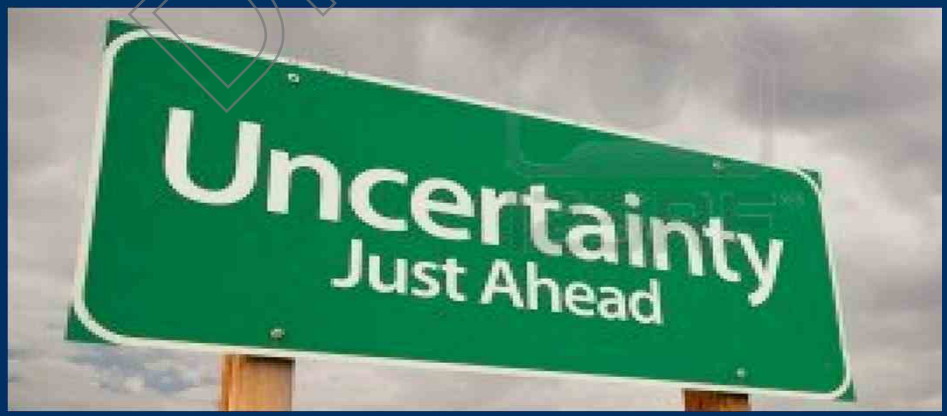
I have the following potential conflicts of interest to report:

- ☐ Consulting
- ☐ Employment in industry
- ☐ Stockholder of a healthcare company
- ☐ Owner of a healthcare company
- ☐ Other(s)

- ☐ I do not have any potential conflict of interest

ACST 2

- ACST-2 is currently the largest trial ever conducted to compare CAS with CEA in asymptomatic pts
- Pts enrolled when revascularization is felt to be clearly indicated
- When CEA and CAS are both possible, but where there is substantial uncertainty as to which is most appropriate



ACST-2

- As the trial will continue for some years, only blinded results have been published up to now

but ….

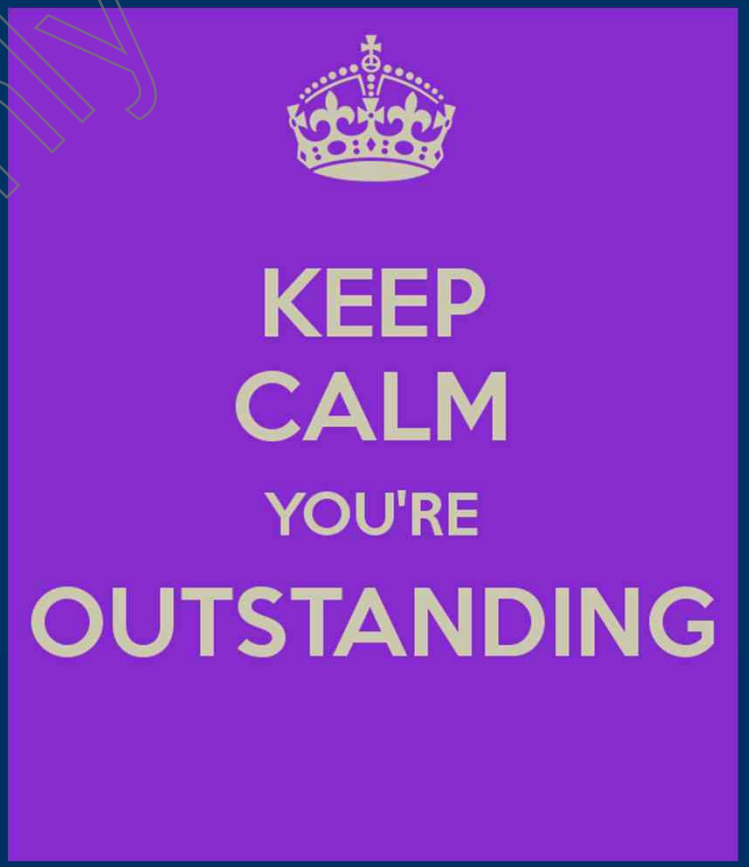
EJVES Nov 2013 ;46(5):510-8

ACST-2

- Results are really outstanding!!

1.0 %

Serious cardiovascular event rate of periprocedural (within 30 days) disabling stroke, fatal myocardial infarction, and death at 30 days



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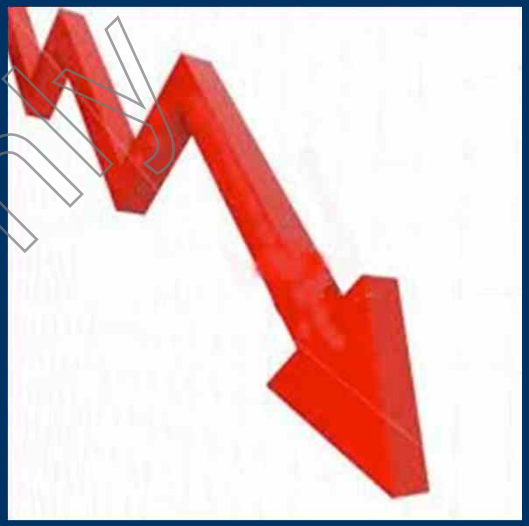
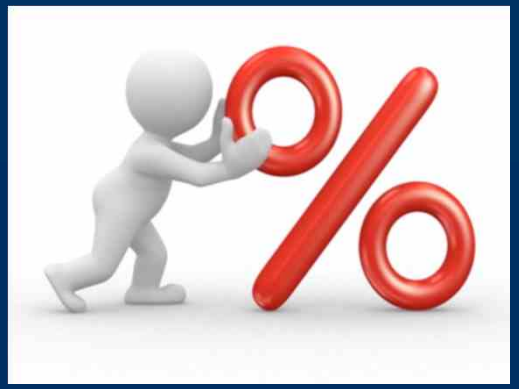
ACST-2

- In ACST-1 CEA caused disabling stroke and death in 1.7% patiens

- ACST-2 patients are generally older and more are diabetic, but disabling stroke and death rate after CEA/CAS was only 1.0%





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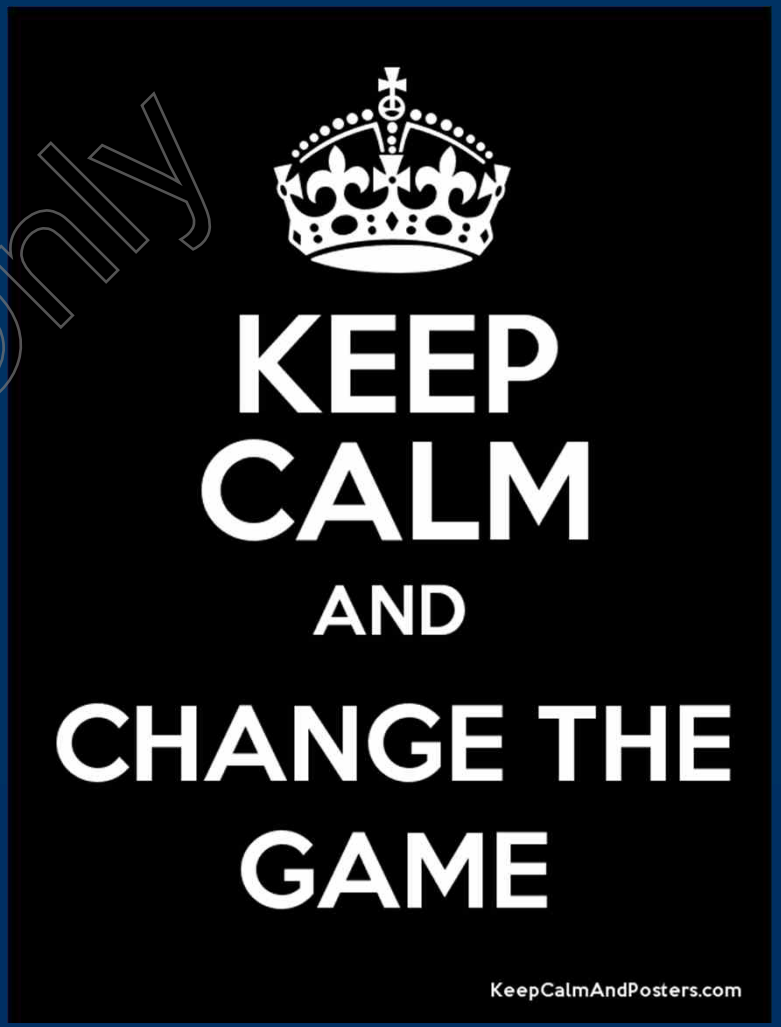
ACST-2

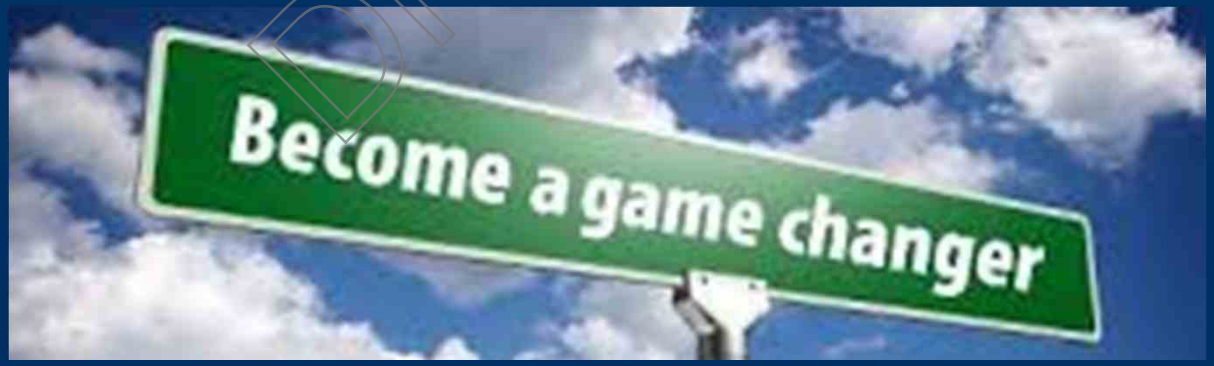
- So, is improved CAS experience leading to improving results?
- Can ACST II change the game?



ICCS long term results

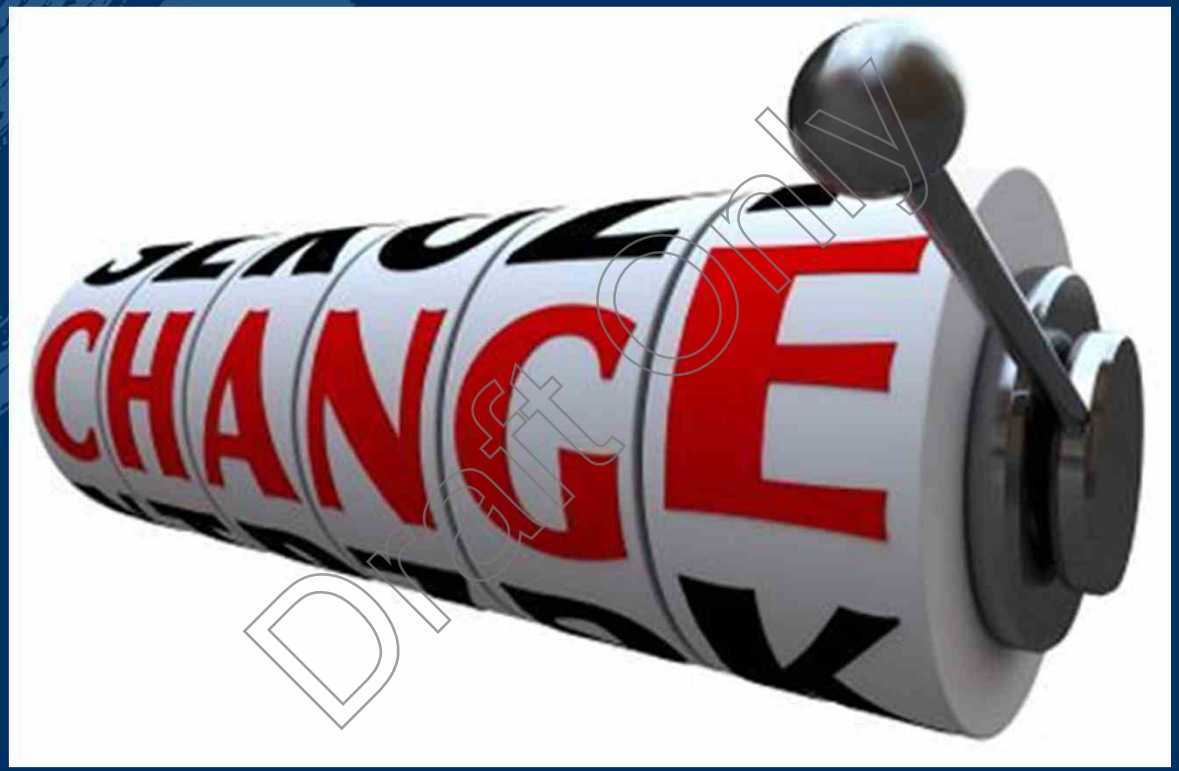
- Previous differences in peri-procedural non-disabling outcome events had favoured CEA;

- After median follow-up of 4 years, both procedures have similar long-term disability, quality of life and restenosis rates.



ICCS long-term result at European Stroke Conference in London, May 2013.

ACST-2



Can ACST-2 really change the game?

ACST-2

Track record

- Doctors must have performed 25 or more of the particular procedure in order to participate in the trial, but their overall experience will be taken into account.

- In general collaborators should have
  - 8% stroke and death risk for symptomatic patients
  - 4% stroke and death risk for asymptomatic patients

EJVES 2009; 38: 239-242

Characteristics of a fair CAS vs. CEA trial

- enrollment should take place only at centers ***proficient*** in ***both revascularization*** modalities
- patients at high-risk for either procedure should be excluded from the randomized trial but may be followed in parallel prospective registries.
- Age *per se* should not be an exclusion criterium.
- The use of EPD should be mandatory
- The primary endpoint of the study should be a composite of death, MI, or stroke at 30 days after the procedure.

Roffi M, Cremonesi A, Setacci C. Proving the safety of carotid artery stenting: **now or never**. J Endovasc Ther 2012

Carotid Artery Stenting: First Consensus Document of the ICCS-SPREAD Joint Committee

Stroke

Alberto Cremonesi, MD; Carlo Setacci, MD; Angelo Bignamini, MD; Leonardo Bolognese, MD; Francesco Briganti, MD; Germano Di Sciascio, MD; Domenico Inzitari, MD; Gaetano Lanza, MD; Luciano Lupattelli, MD; Salvatore Mangiafico, MD; Carlo Pratesi, MD; Bernard Reimers, MD; Stefano Ricci, MD; *Gianmarco de Donato*, MD; Ugo Ugolotti, MD; Augusto Zaninelli, MD Gian Franco Gensini, MD

Stroke.2006; 37: 2400-2409

CAS: First Consensus Document of the ICCS-SPREAD Joint Committee

CAS: Training and Expertise

Recommendation 10: Grade GPP [C]

Once the basic skill for catheter-based intervention has been achieved by the already-active interventionist, the minimum reccomended training to achieve competence is as follows:

1. At least 150 procedures of supra-aortic vessel engagement (during diagnostic as well as interventional procedures) within 2 years, of which at least 100 as the primary operator.
2. At least 75 carotid stenting procedures, of which at least 50 as the primary operator , within a 2-year fellowship.

Recommendation 11: Grade GPP [C]

The minimum requirement to maintain technical skill (competence) is the number of 50 carotid stenting procedures performed and documented by each primary operator per year.

Stroke

Stroke.2006; 37: 2400-2409

Experience

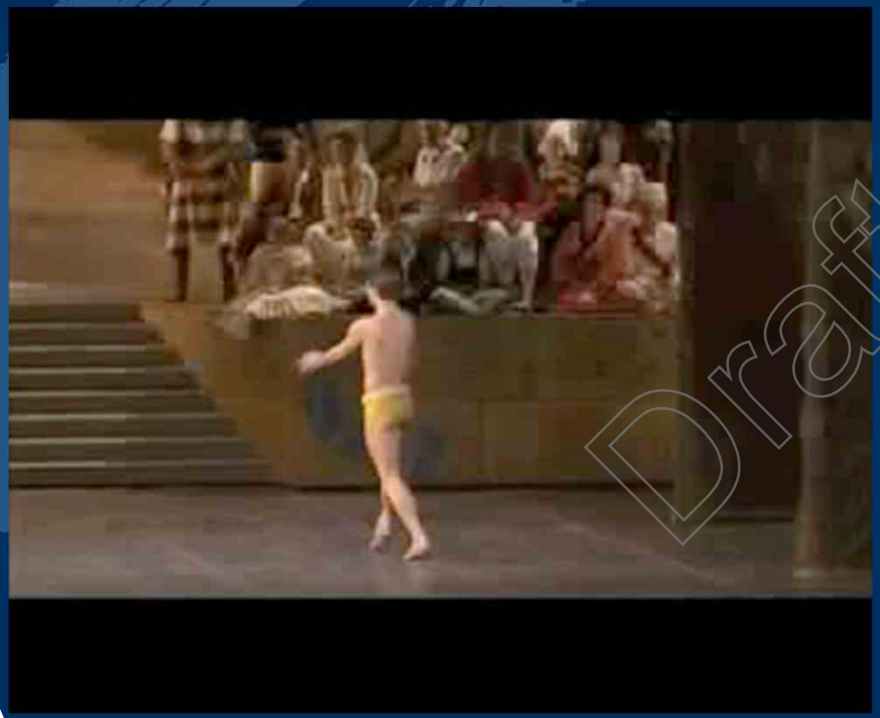
A pooled randomised trial (3 RCTs: EVA 3S + SPACE + ICSS) analysis by the Carotid Stenosis Trialists' Collaboration (CSTC) found that peri-procedural risk for CAS fell when collaborators' volume of work increased

Operator	Stroke/death at 30 days
Lowest-volume	10.1%
Intermediate-volume	8.4%
Highest-volume	5.1%

European Stroke Conference in London, May 2013.

experience

Result of intensive training



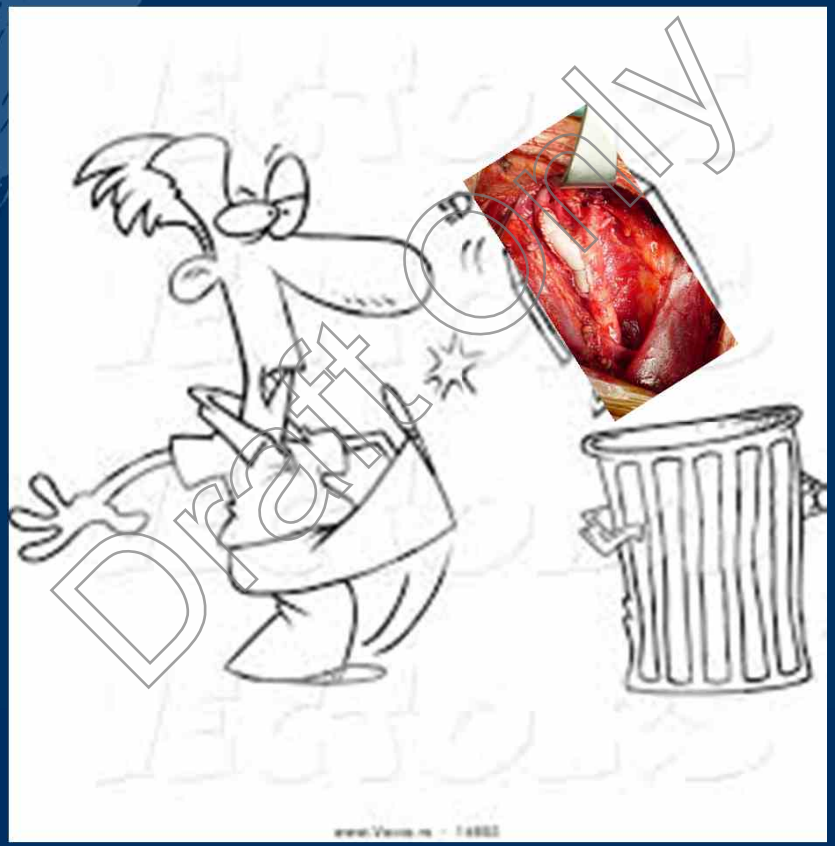
Result of poor training

Can ACST II change the game?

Yes, it can.

But, what will the new rules be?

Can ACST II change the game?

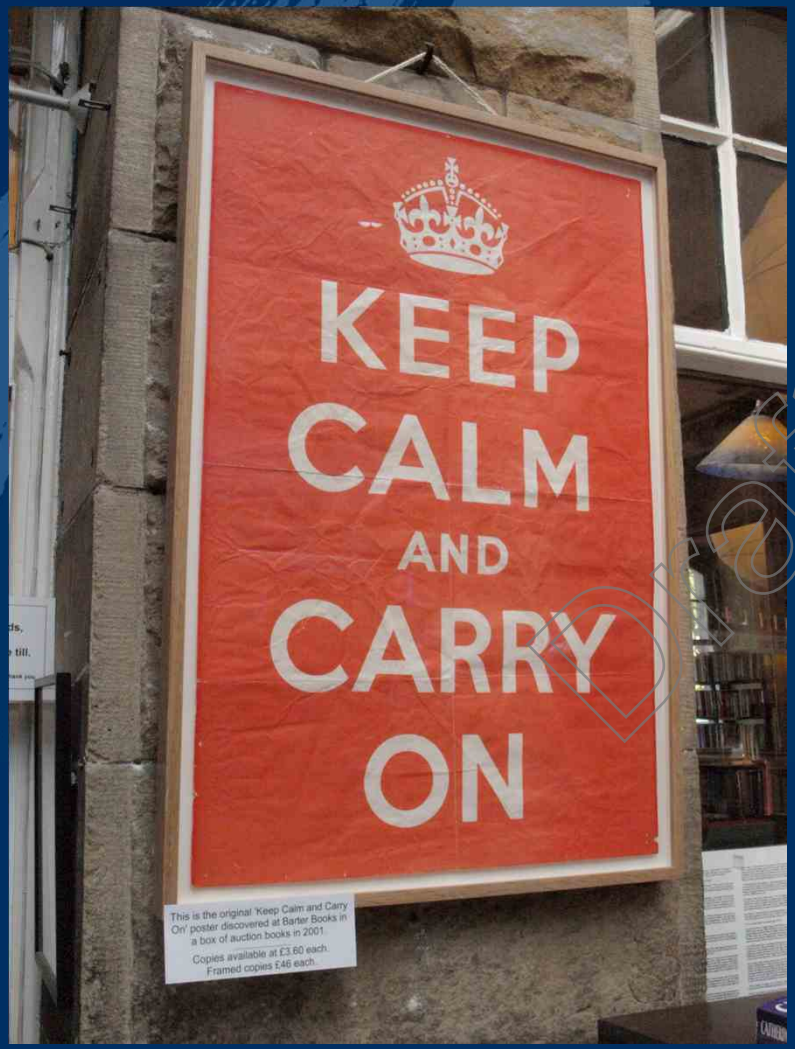


Nobody will ever throw CEA away!

Message from ACST-2

- In a centre having a collaborating neurologist (or stroke physician), vascular surgeon and stenting interventionalist (which may be a surgeon, a radiologist, cardiologist, or physician with specialist training in carotid stenting) *both CEA and CAS are safe and effective* in asymptomatic patients

Message from ACST-2



"Motivational poster produced by the British government in 1939, several months before the beginning of the Second World War, intended to raise the morale of the British public in the aftermath of widely predicted mass air attacks on major cities"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