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2 MDs, 4 Nurses, 6 Priests

Our experience with both ACST trials – why Reggio Emilia is special

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WHY ACST-1

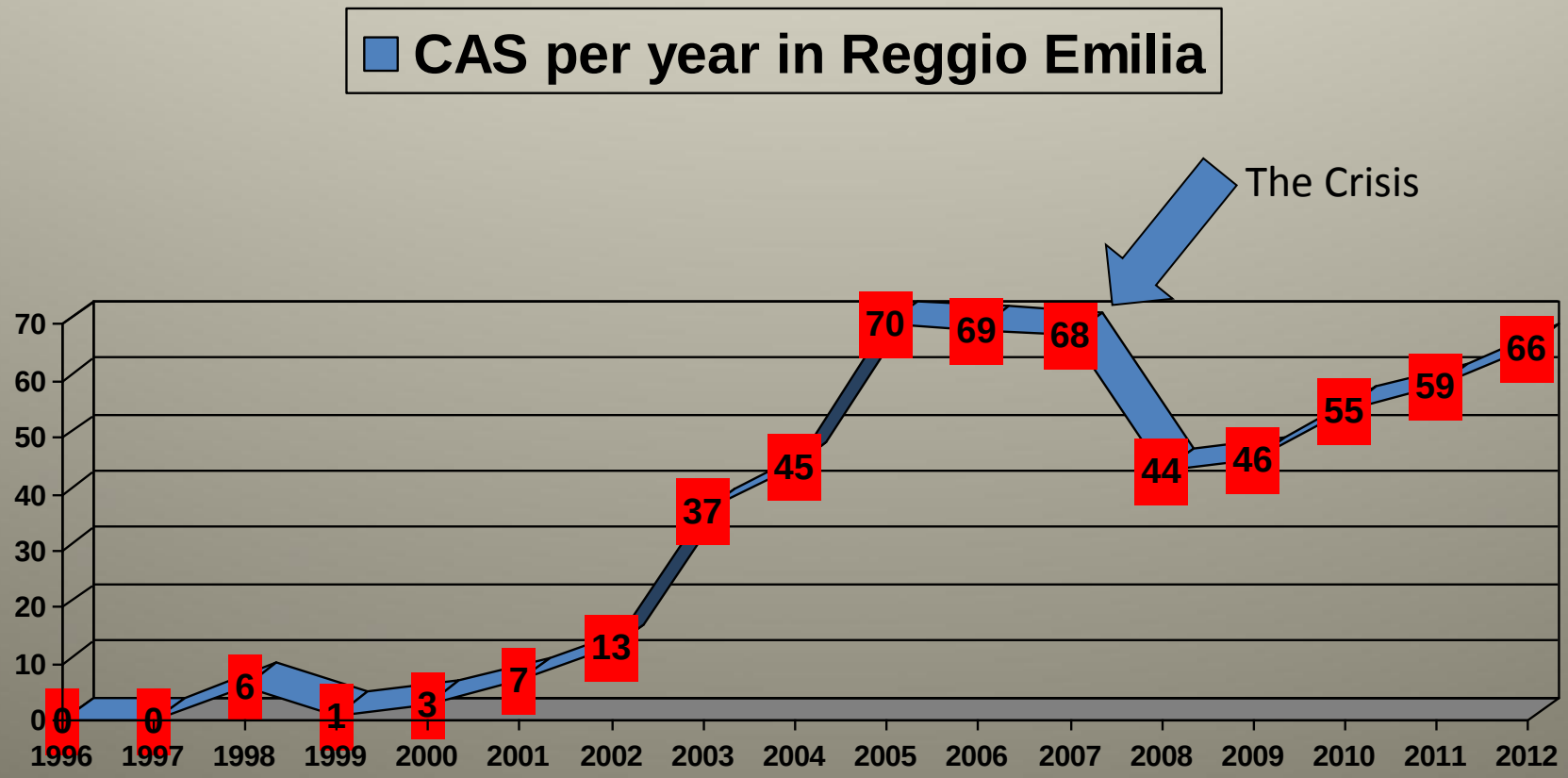
- Our team in the ‘90s performed ~ 300 CEA/yr
- We chose local anesthesia, pre-operative ecoduplex scan
- eversion with reimplantation of ICA was our gold standard (~95% of cases)
- A high rate of asymptomatic patients (70%)
- We work in a public hospital /small town/ high volume of procedures: limited time for research
- The selling point of the trial was its simplicity (especially in f-up)
- Possibility to confront our experience with worldwide surgical teams
- Enthusiasm in research

WHY ACST-1

- Between 1993 and 2003, 3120 asymptomatic patients from 126 centres in 30 countries
- Between January 1994-June 1996 we randomized 51 patients
- Allocation: 26 - BMT , 25 - CEA
- Perioperative risk of stroke or death of the trial within 30 days was 3.0%
- Our CEA peri-operative risk of Stroke/Death at the time was 1.2 %
- At our centre 17 of the 26 BMT pts (f-up of 20 mths) 7 pts were treated: 5 for symptoms, and 2 for plaque progression

After ACST-1

- We continued with Asymptomatic CEA with the same philosophy: local an., ecoduplex selection
- We started a new adventure in the 90's with CAS : a new treatment ?



WHY ACST-2

- Lack of Spontaneous/RT Literature
- Absence of indication in the Asymptomatic patient
- The time changes the CAS-option: new device, selection of patients , AngioCT-always, MoMa block flow protection, dual mesh stent, skillfullness in vascular surgeons due to the learning curve, double antiplatelet therapy
- The Trial perception in our Team changed… from Experimental to a new possible treatment for patients
- As a consequence of the new life to the CAS... A new life for the Trial
- Still a simple trial
- Enthusiasm is still the same: proposed to other groups
- Transformation from Me to Us of my experience

WHY ACST-2

- Questions to the research staff: any changes?
- A new approach in Symptomatic soft plaque
- After Thrombolisis in acute Stroke
- After the end of the Trial what will happen ?
- What should ACST-3 be?

Canonis libri V. Traduzione in latino di
Gerardus Cremonensis (AVICENNA)
Patavini, s.t. [i.e. Johannes Herbort], 1479
Arcispedale Santa Maria Nuova Library

The *Canon* contains seven rules for experimenting with a new Device

1. "The Stent must be plenty of all acquired quality"; for example dual mesh
2. "The experiment mustbe done on a single, not a composite surgeon"; in other words it should not be tested on a patient without skill in cerebral protection devices.
3. "The stent must be tested on two contrary conditions"; a stent may act directly on a disease but also it may be effective against a different disease by relieving its symptoms : soft and hard plaque
4. "The quality of the stent must correspond to the strength of the disease...it is best to experiment first using the simple cases and then increase it gradually until you know the potency of the stent, leaving no room for doubt."
5. "One should consider the time needed for the stent to take effect. If the stent has an immediate effect, this shows that it has acted against the disease itself.”
6. "The effect of the stent should be the same in all cases or, at least, in most. If that is not the case, the effect is then accidental, because things that occur naturally are always or mostly consistent."
7. "Experiments should be carried out in RT ..the quality of the medicine might mean that it would affect the human body differently from the animal body.

Conclusion