THE TYRANNY OF P VALUES
THE IMPORTANCE OF KNOWING DETAILS OF RCTS

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NEW TREATMENTS MAY OR MAY NOT BE BETTER THAN EXISTING ONES
NEED STATISTICAL COMPARISONS TO DISCERN RELATIVE DIFFERENCES BETWEEN APPROACHES
RANDOMIZED CONTROLLED TRIALS ARE THE BEST METHOD FOR DOING THIS

DISCLOSURES
- ABBOTT VASCULAR: CONSULTANT
- SYNTACTX (NELLIX): DSMB

RCTS IN VASCULAR DISEASE MANAGEMENT
- CAROTID
  - SYMPTOMATIC (EAO, NASCET, ECST)
  - ASYMTOMATIC (ACAS, VA, ACST I, II, CASANOVA)
  - STENT (EV3, ICSS, SAPPHIRE, CRESTM I & II)
- AORTIC ANEURYSM
  - SMALL (ADAM, UK, PIVOTAL)
  - EVAR (EVAR I & II, OVER, DREAM, IMPROVE, AJAX)
- CRITICAL LIMB ISCHEMIA
  - BASIL
  - BEST

DIFFICULT TO DESIGN
- MULTIPLE STAKE HOLDERS
- CLEAR INCLUSION / EXCLUSION CRITERIA
- OBJECTIVES / ENDPOINTS (CREEP)
DIFFICULT TO CONDUCT
- MULTIPLE INVESTIGATORS, INSTITUTIONS
- LARGE DATA SETS
- CONTROLS (DATA, CORE-LAB, DSMB)
TIMELINESS ISSUES
- RECRUITMENT

DATA MANAGEMENT
  - ACQUISITION
  - VERIFICATION
  - ADJUDICATION
  - ANALYSIS
    - PRIMARY / SECONDARY END-POINTS
    - SUB GROUP ANALYSES
    - STRENGTH OF EVIDENCE
PRESENTATION AND PUBLICATION
  - MEETING, JOURNAL, PRESS
**P VALUE**

- Based on probability
- Level of statistical significance
  - Generally 0.05 or less
- Represents point value within a range
- Interpretation errors common
- $P > 0.05$ does not prove absence of effect
- $P < 0.05$ does not prove an effect and may conflict with common sense or be clinically irrelevant

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**Tyranny of P Value**

- Clopidogrel vs Aspirin in patients with PAD
  - 19,185 patients
  - Stroke, MI, vascular death
  - Annual risk
    - 5.32% vs 5.83%
    - RR = 0.5% $P = .043$ (95% CI 0.02-0.9%)
    - RRR = 8.7% (95% CI 0.3-16.5)
    - NNT 200-5000

**Conclusion**

- Clopidogrel superior to aspirin
  

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**Summary**

- RCTs provide important clinical evidence
- RCTs can have flaws
- Use caution in their interpretation
- Read the fine print

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**Challenges to Practitioners**

- Understand methodology
- Understand results
  - Hypothesis proven
  - Strength of evidence
  - Applicability
    - In general
    - Specific patient

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**Conclusion**

- P value is one thread string of evidence in clinical decision making