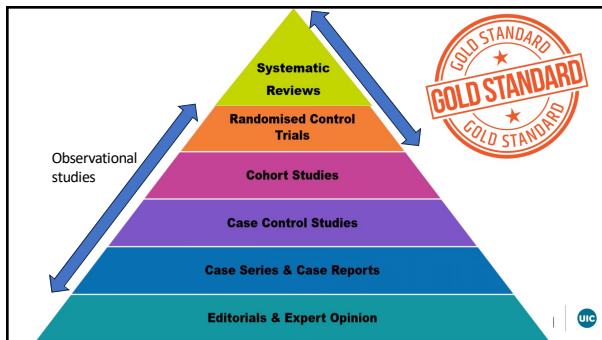


Why RCTs In Vascular Surgery In The Era Of AI Are Unnecessary, Useless And Possibly Unethical

Willem Wisselink, MD FACS
University of Illinois Hospital
Chicago

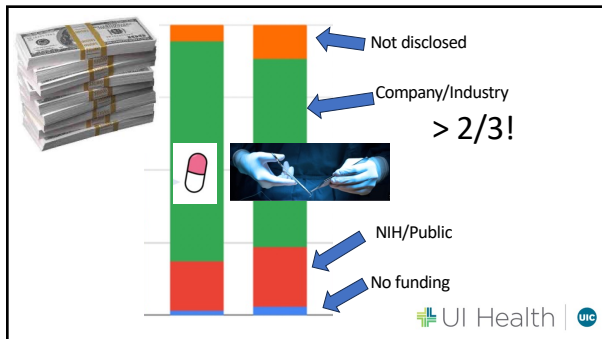


No Disclosures

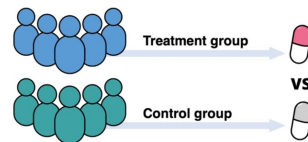


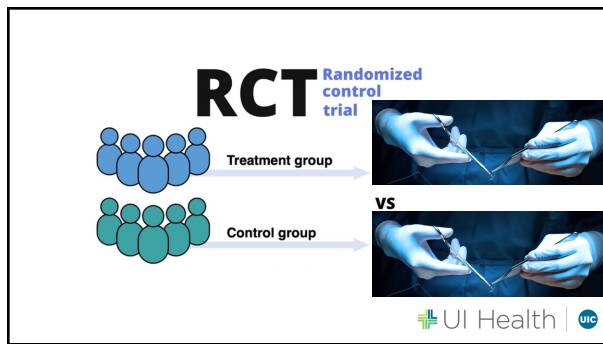
What's needed for an RCT?

- Equipoise
- Random assignment
- Credible control
- Well-defined research question
- Defined inclusion and exclusion criteria
- Blinding
- Unbiased analysis
- Registration
- Disclose funding sources



RCT Randomized control trial





Netherlands

- 1st RCT: Streptomycin for TBC: 1940ies
- Country with the highest relative volume of published surgical RCTs is the Netherlands

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THE NEW ENGLAND JOURNAL OF MEDICINE

A Randomized Trial Comparing Conventional and Endovascular Repair of Abdominal Aneurysms

Endovascular Repair Versus Open Repair of Ruptured Abdominal Aortic Aneurysms

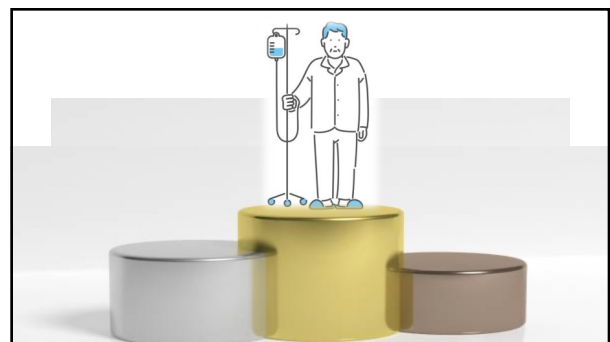
A Multicenter Randomized Controlled Trial

Correspondence Section

RESEARCH LETTER

Coeliac Artery Release or Sham Operation in Patients Suspected of Having Median Arcuate Ligament Syndrome: The CARoS study

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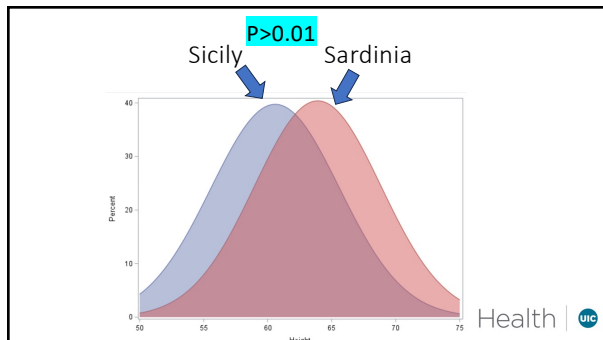
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Equipoise



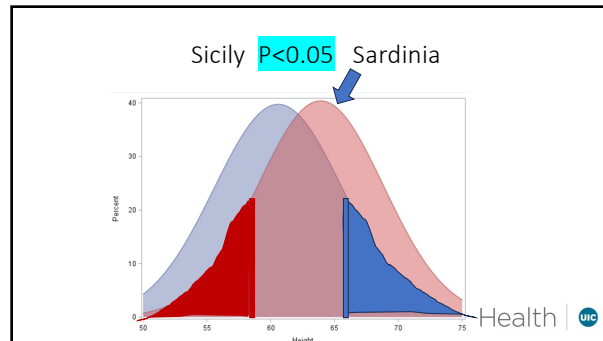
Randomized trial

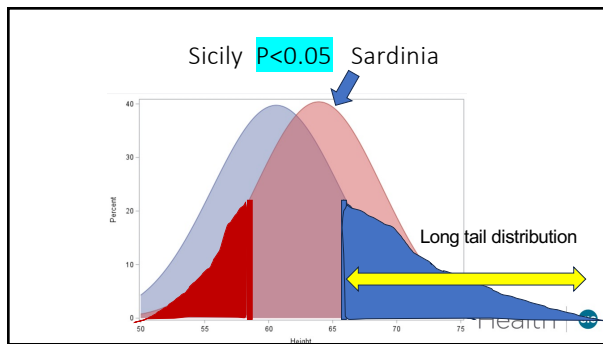
200 volunteers, test visit



Evidence Based Conclusion:

- Sardinia is the better destination!





What would be better?

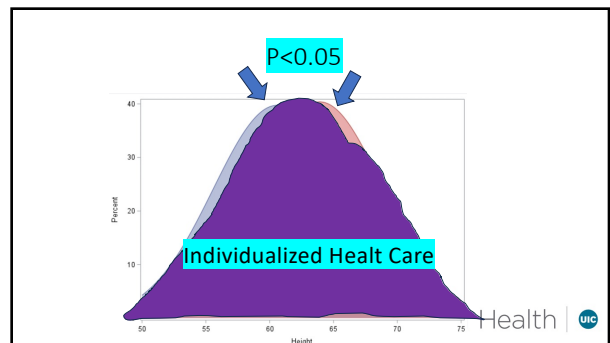
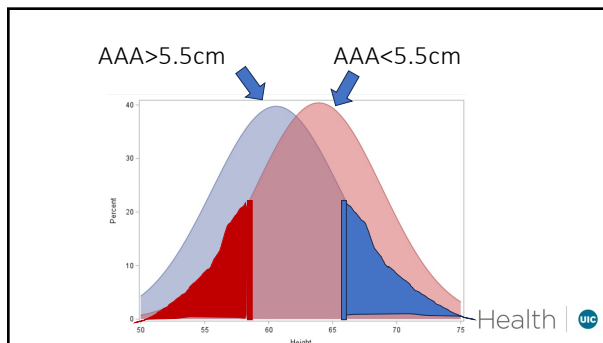
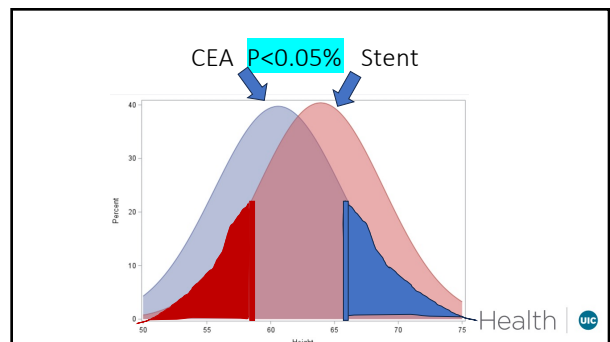
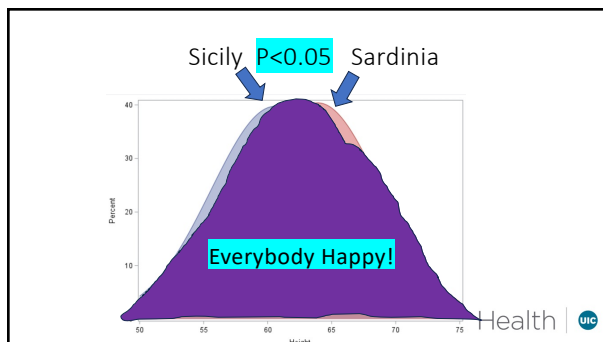
N=1 trial:

Each and every tourist travels to both islands and decides what's best.

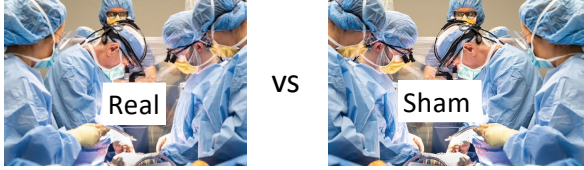
We do this for every tourist

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This text block is contained within a black-bordered box. It poses a question, defines an 'N=1 trial' as a process where each individual makes their own choice, and states that this is done for every tourist. The 'Health | UIC' logo is in the bottom right corner.



N=1 trial for surgery is cumbersome



Real vs Sham

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Conducting Clinical Trials in Twin Populations: A Review of Design, Analysis, Recruitment and Ethical Issues for Twin-Only Trials

Published online by Cambridge University Press: 25 January 2022



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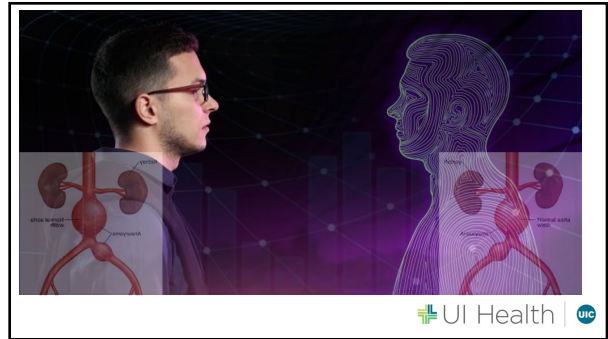
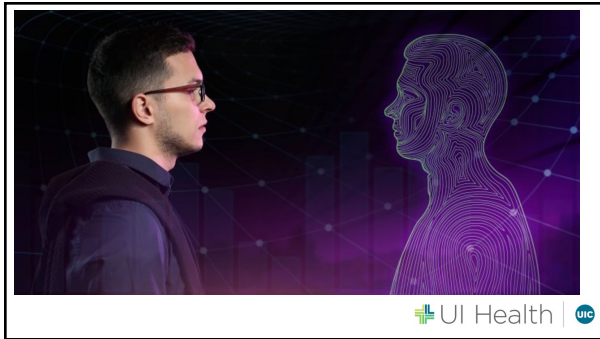
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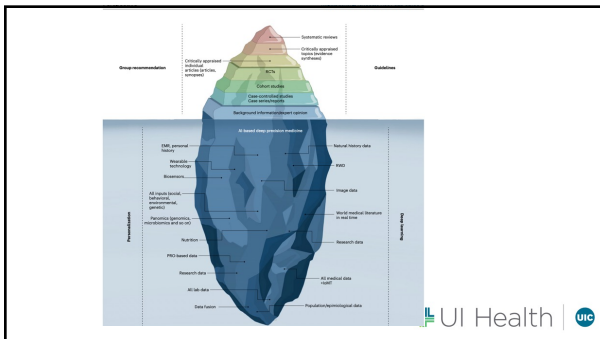
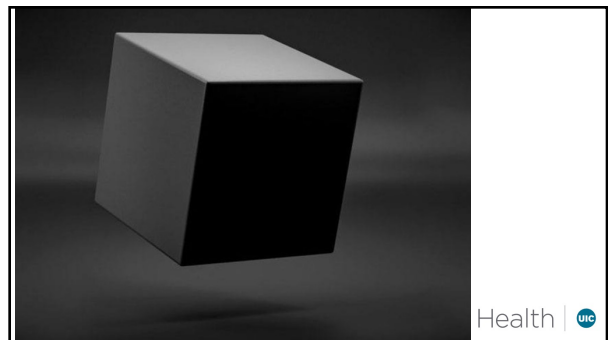


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Big Data

- Huge amounts of data from electronic health records, imaging and wearable devices
- Registries (the International Consortium of Vascular Registries (ICVR) VASCUNET, SVS VQI, UK Vascular Services Quality Improvement Programme (VSQIP)
- VASCUL-AID Platform, EU funded project led by Dr. KK Yeung



Artificial Intelligence

Sophisticated machine learning algorithms

↓

Customised Surgical Care
Precision Medicine

What's the evidence for all of this?



Randomised controlled trials evaluating artificial intelligence in clinical practice: a scoping review

Ryan Han, Julián N Acosta, Zahra Shakeri, John P A Ioannidis, Eric J Topol*, Pranav Rajpurkar*



Conclusions

- Big data, AI and machine learning offer the potential to develop robust individual predictive algorithms
- By analyzing millions of historic surgeries along with patient characteristics, AI will allow surgeons to accurately stratify the risks of a particular surgery for a specific patient
- Although we're not quite there yet, we will soon look back at surgical randomized trials as obsolete and unethical

