

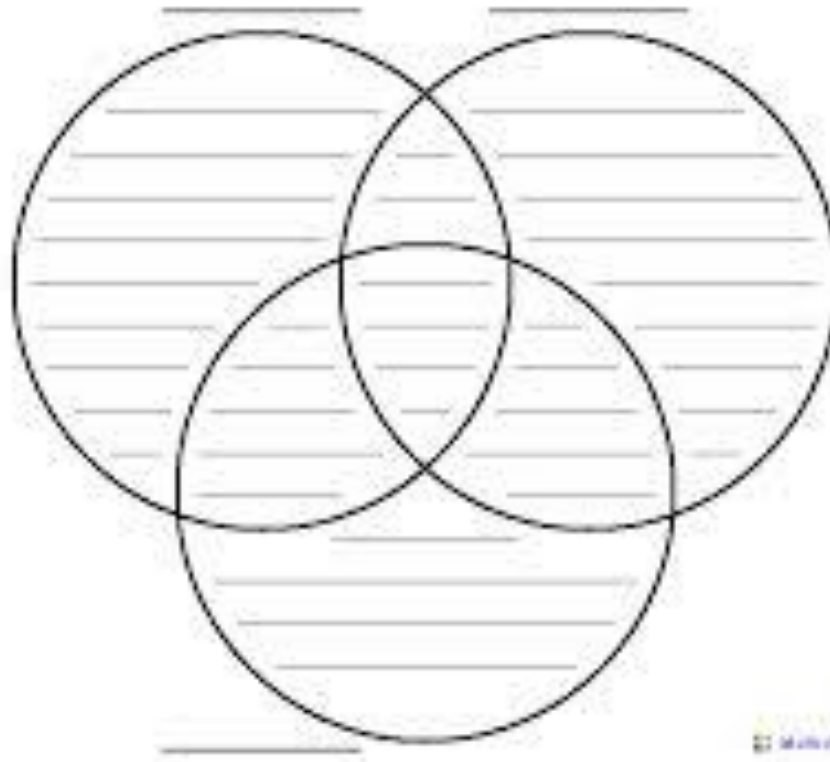
Designing a Study- So Many Choices

Stacie Deiner M.D.

Associate Professor of Anesthesiology,
Neurosurgery, Geriatrics and Palliative
Care

What is the best study?

Name: _____ Venn Diagram



How to get started

- ? What do you observe every day?
- Case reports

Prevention of Airway
Injury During Spine
Surgery: Rethinking
Bite Blocks

To JNA Readership:



FIGURE 1. Toothette Adult Bite Block (Sage Medical Products Inc) placed between the molars opposite to the endotracheal tube and taped in place.

Case Report

Pro

- Easy data
- No statistical analysis
- AA case report journal

Con

- May need patient consent
- Generally not peer reviewed

Case Series

- Series of patients you observe with a particular condition of interest
- Does not involve an intervention done for the purpose of research
- Could be prospective or retrospective

Clinical Study

Anesthesia for Pediatric Deep Brain Stimulation

Joseph Sebeo,¹ Stacie G. Deiner,¹ Ron L. Alterman,² and Irene P. Osborn¹

¹*Department of Anesthesiology, Mount Sinai School of Medicine, One Gustave L. Levy Place, New York, NY 10029, USA*

²*Department of Neurosurgery, Mount Sinai School of Medicine, One Gustave L. Levy Place, Box 1136, New York, NY 10029, USA*

2. Materials and Methods

After obtaining IRB approval, the anesthetic records from 28 pediatric DBS cases were reviewed. The following technique was used.

Case Series

Pro

- Uses data you already have
- Basic statistics you could do using Excel (mean, median, SD etc...)
- May be a “brief report format”

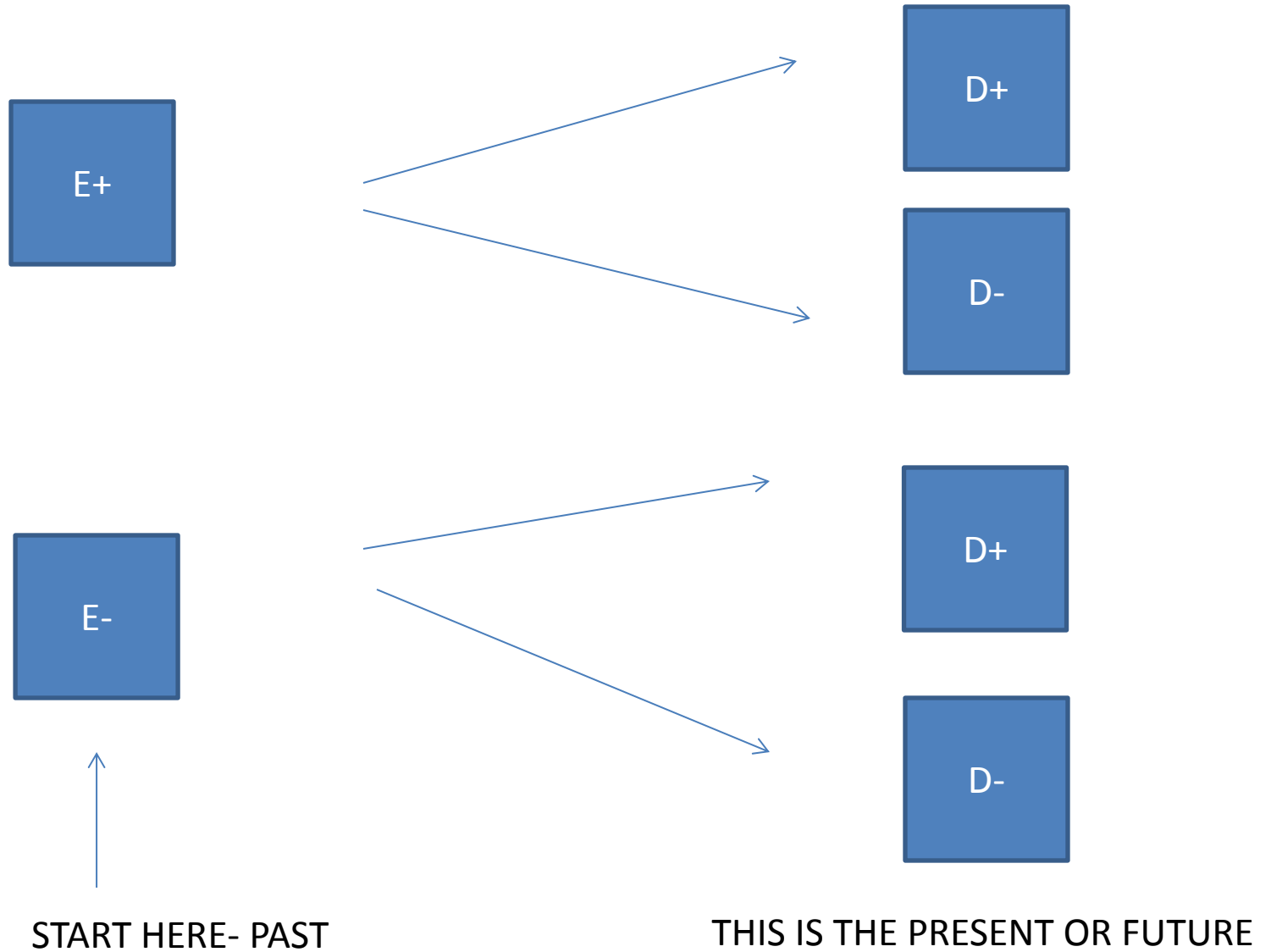
Con

- Will require IRB approval
- No assignment of techniques or treatments
- May be some bias based on provider decision making/skill

Cohort study

- Start with disease -free individuals
- Compare those exposed and unexposed to a risk factor
- Measure the proportion of each group which develops the disease
- Can be prospective or retrospective

Retrospective Cohort Study



Examples –Retrospective Cohort

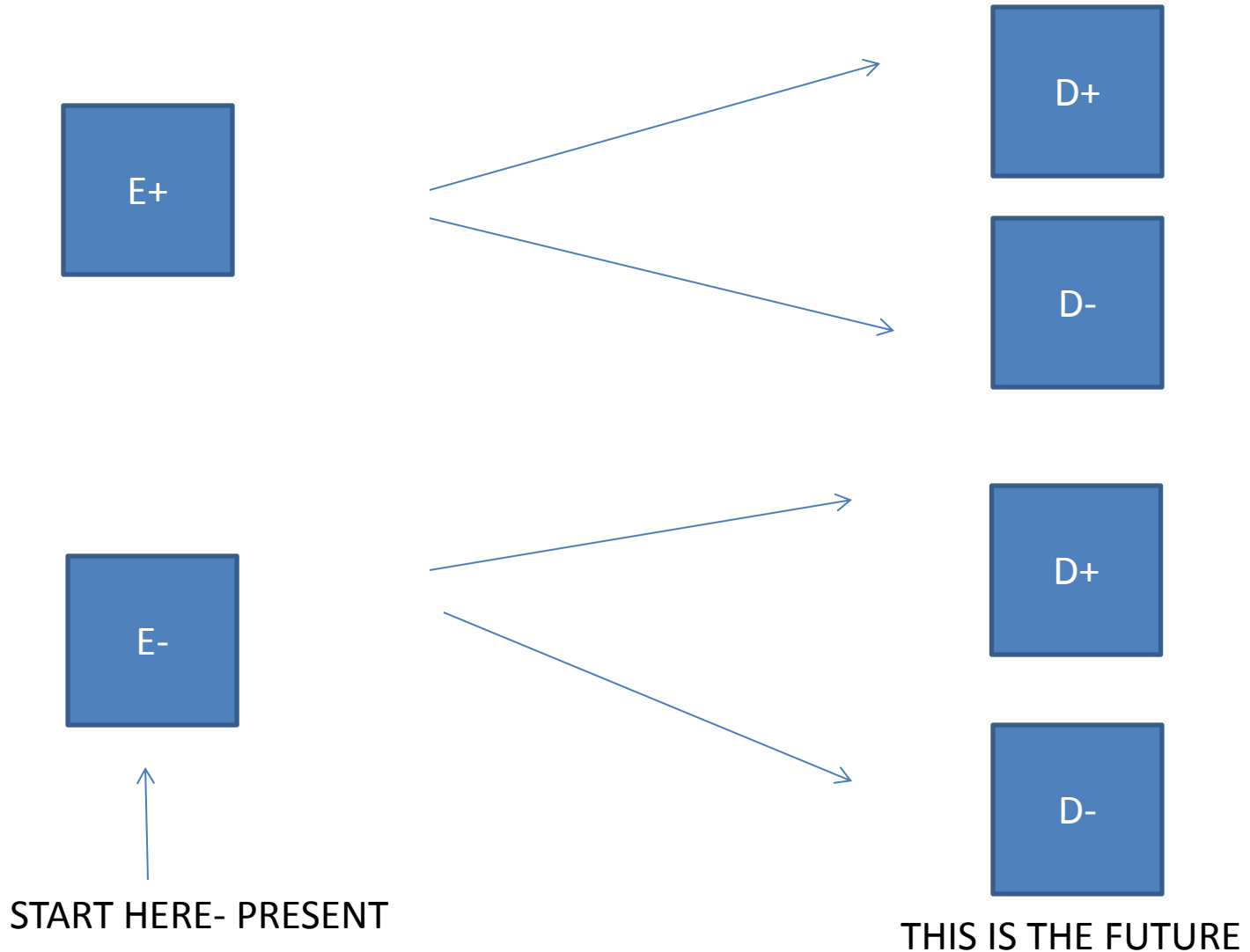
Cumulative Duration of “Triple Low” State of Low Blood Pressure, Low Bispectral Index, and Low Minimum Alveolar Concentration of Volatile Anesthesia Is Not Associated with Increased Mortality

Miklos D. Kertai, M.D., Ph.D., William D. White, M.S., M.P.H., Tong J. Gan, M.D., M.H.S., F.R.C.A.

Predictors of long-term shunt-dependent hydrocephalus in patients with intracerebral hemorrhage requiring emergency cerebrospinal fluid diversion

BRAD E. ZACHARIA, M.D.,¹ KERRY A. VAUGHAN, B.A.,¹ ZACHARY L. HICKMAN, M.D.,¹ SAMUEL S. BRUCE, B.A.,¹ AMANDA M. CARPENTER, B.A.,¹ NILS H. PETERSEN, M.D.,² STACIE DEINER, M.D.,³ NEERAJ BADJATIA, M.D.,² AND E. SANDER CONNOLLY JR., M.D.¹

Prospective Cohort Study



Example Prospective Cohort

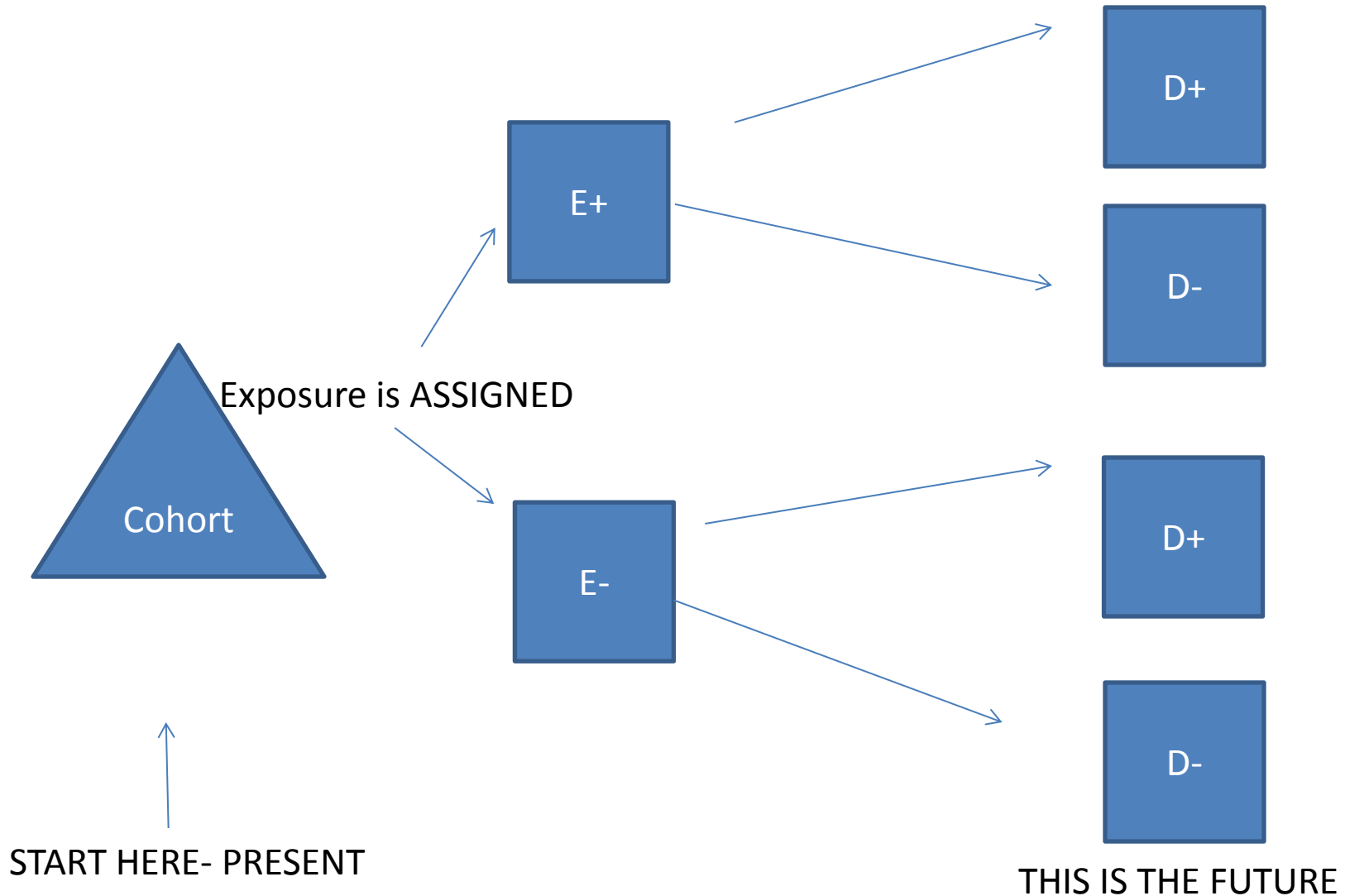
Original Research Article

Do Stress Markers and Anesthetic Technique Predict Delirium in the Elderly?

Stacie Deiner^{a-c} Hung-Mo Lin^d Daniella Bodansky^a
Jeffrey Silverstein^{a, c} Mary Sano^e

Departments of ^aAnesthesiology, ^bNeurosurgery, ^cGeriatrics and Palliative Care, ^dHealth Evidence and Policy, and ^ePsychiatry, Icahn School of Medicine at Mount Sinai, New York, N.Y., USA

Randomized Controlled Trial



How to

- Define your question
- Define your source population
- Measure the exposure
- Follow the cohort
- Classify the outcome

Cohort Study

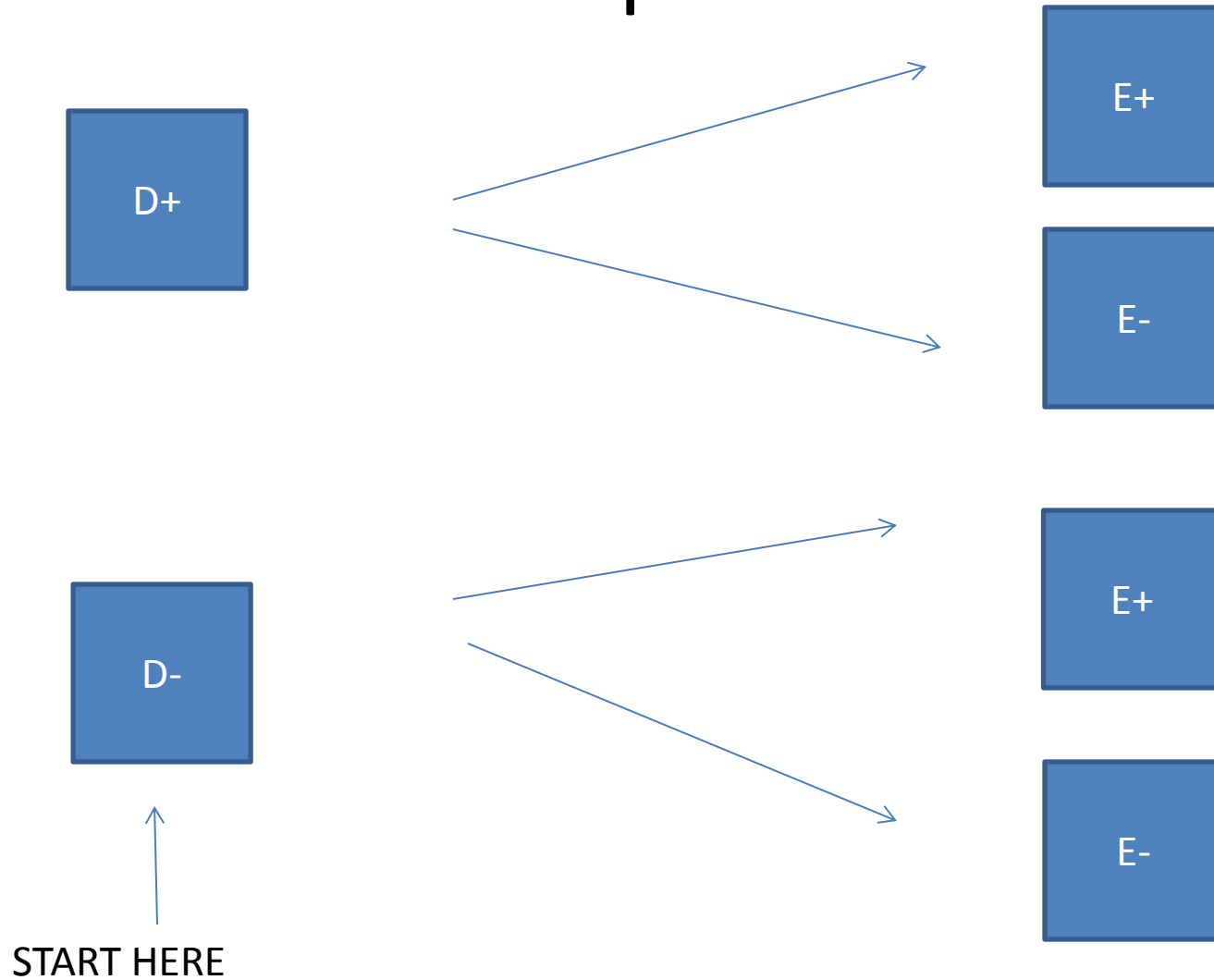
Pro

- Allows for more sophisticated analysis
- Does not randomize patients
- “If you can’t control it, measure it”
- Randomization minimizes confounding factors (RCT)

Con

- Needs IRB approval
- May require more complicated statistics
- Beware of confounding
- Beware of external validity

Case Control Study- pro or retrospective



Example RCT

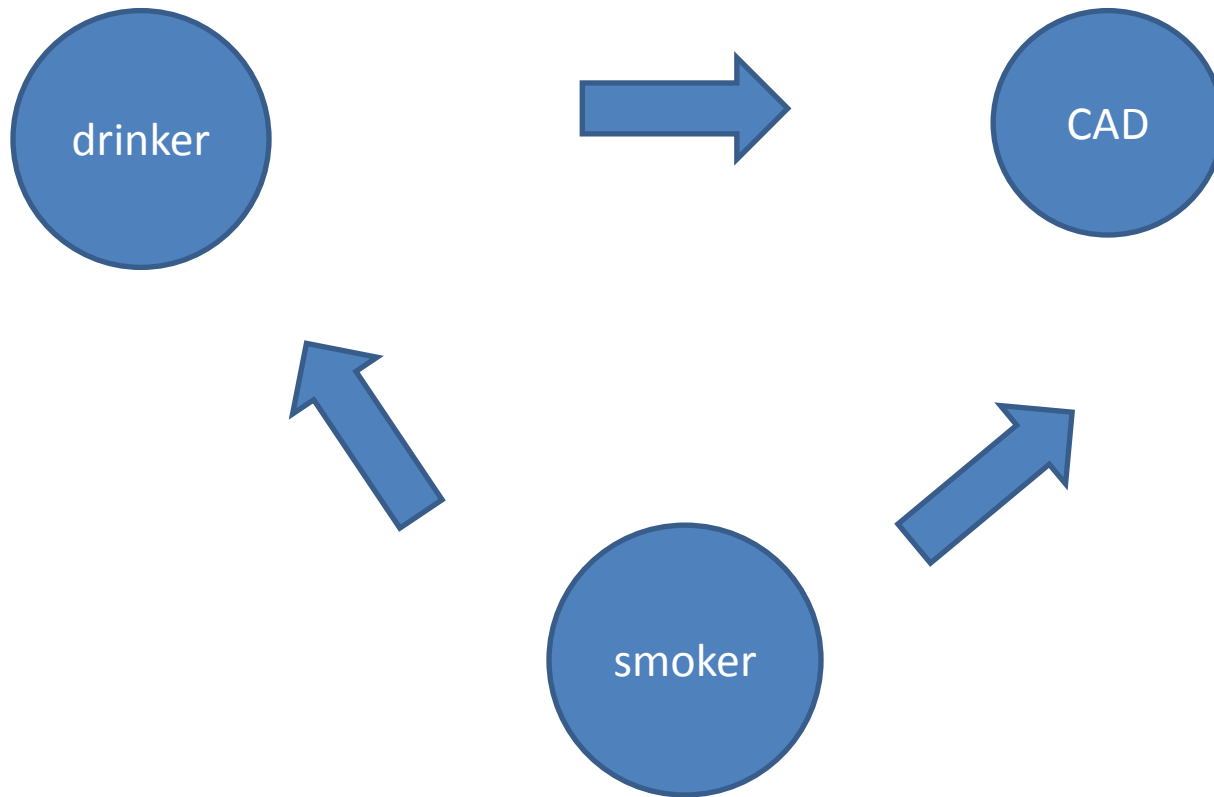
Is Depth of Anesthesia, as Assessed by the Bispectral Index, Related to Postoperative Cognitive Dysfunction and Recovery?

Ehab Farag, MD, FRCA*
Gordon J. Chelune, PhD†
Armin Schubert, MD, MBA*
Edward J. Mascha, PhD§

We randomized 74 patients to either a lower Bispectral Index (BIS) regimen (median BIS, 38.9) or a higher BIS regimen (mean BIS, 50.7) during the surgical procedure. Preoperatively and 4–6 wk after surgery, the patients' cognitive status was assessed with a cognitive test battery consisting of processing speed index, working memory index, and verbal memory index. Processing speed index was 113.7 ± 1.5 (mean \pm SE) in the lower BIS group versus 107.9 ± 1.4 in the higher BIS group ($P = 0.006$). No difference was observed in the other two test battery components. Somewhat deeper levels of anesthesia were therefore associated with better cognitive function 4–6 wk postoperatively, particularly with respect to the ability to process information.

(Anesth Analg 2006;103:633–40)

Confounding



Secondary data analysis

- Special case – may get to work with de-identified data
- E.g. NSQIP
- Can be free (NSQIP) or quite expensive (Medicare)
- Get access to large amount of data
- But can only ask a question from data already collected

Examples

Can Routine Preoperative Data Predict Adverse Outcomes in the Elderly? Development and Validation of a Simple Risk Model Incorporating a Chart-Derived Frailty Score

Levana G Amrock, BS, Mark D Neuman, MD, MSc, Hung-Mo Lin, ScD, Stacie Deiner, MD, MS

Another example

Original Investigation

Anesthesia Technique, Mortality, and Length of Stay After Hip Fracture Surgery

Mark D. Neuman, MD, MSc; Paul R. Rosenbaum, PhD; Justin M. Ludwig, MA; Jose R. Zubizarreta, PhD; Jeffrey H. Silber, MD, PhD

Data Sources

We obtained data on acute care hospital discharges between January 1, 2004, and December 31, 2011, from New York's State-wide Planning and Research Cooperative System (SPARCS). Our data set included unique patient identifiers and indicators of 30-day mortality. We obtained hospital characteristics data from the 2006 American Hospital Association Survey and data on zip code area characteristics from census files. The study

Case Control Study

- Start with people with and without a disease
- Compare prior exposure to a risk factor
- Very important that your controls are “people who if they had gotten the disease would have been cases in your study”
 - Controls must meet the inclusion/exclusion criterion
 - Have the same method of assessing the exposure

Example: Case -control

Long-term postoperative cognitive dysfunction in the elderly: ISPOCD1 study

*J T Moller, P Cluitmans, L S Rasmussen, P Houx, H Rasmussen, J Canet, P Rabbitt, J Jolles, K Larsen, C D Hanning, O Langeron, T Johnson, P M Lauen, P A Kristensen, A Biedler, H van Beem, O Fraidakis, J H Silverstein, J E W Beneken, J S Gravenstein, for the ISPOCD investigators**

Case Control

Pro

- Can be a very efficient way to do a study

Con

- If the controls are not comparable to the cases on all other factors than exposure the premise is void

Where to start?

- Consider your clinical expertise
- Think about how much time you will have
- Consider your mentorship opportunities
- Look at your resources for data

Good studies

- Start with a clear definition of the question
- And a good literature search
- Use your academic librarians and do the search with them
- Meet with a statistician early on to help define your endpoints and data collection

Don't be afraid of the IRB

- Their function is to protect you and your patients
- If you don't know if you need approval- ASK
- Consider a curbside consult if you have questions
- There is standard language expected for recruitment and data management

And some famous words

- “Only investigate questions you are passionate about because no one else will love them the way you do and somewhere in the middle the time and effort will not seem worth it.”

Paraphrased from Dr. Lee Goldman, Dean of the Faculties of Health Sciences and Medicine at Columbia Medical Center

Thanks so much

- Stacie.deiner@mssm.edu
- Come see me and join the discussion at the SNACC POD, POCD special interest group (SIG)