

Kickstarting the Brain: Methodological Challenges of Emerging Technologies

Chairs

Dr Jill Rasmussen, Dr Dawn Velligan

Depression

Issues in Conducting Trials

- Lack of a definitive marker for diagnosis
- A significant number of trials in depression are not focused on answering the most important clinical questions
- Placebo response
- Identifying the correct study population for a successful clinical trial in a heterogeneous disease:
 - Fail to take into account history, demographics

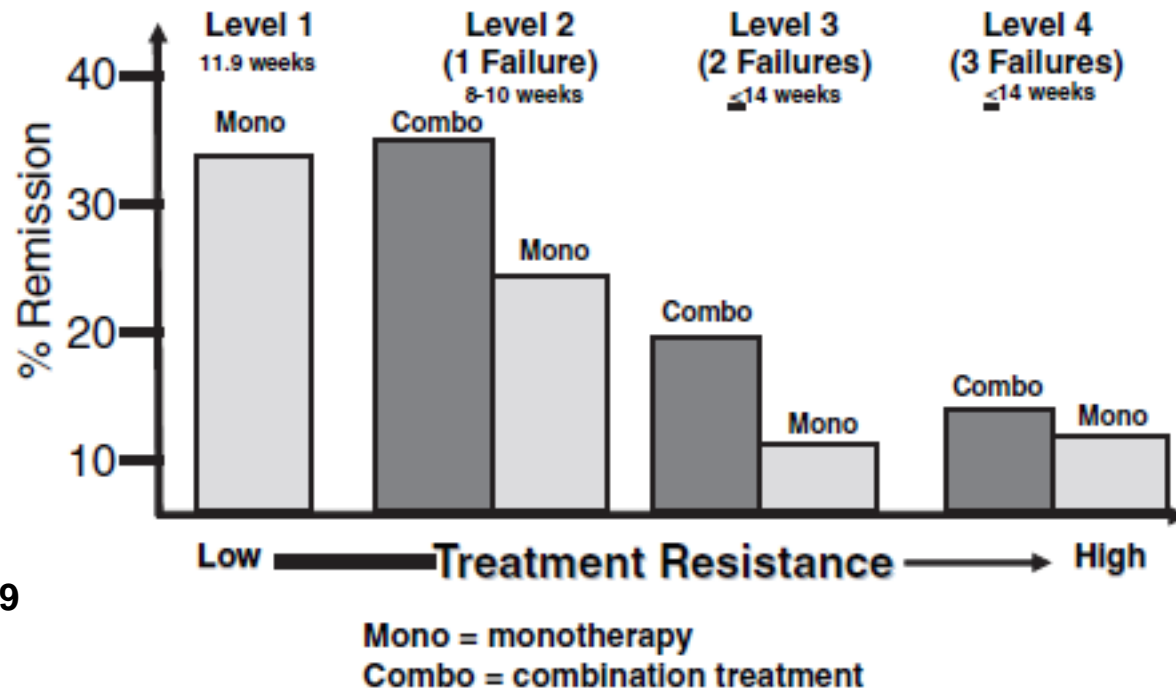
Depression -Treatment Challenges

- Rapid onset of effect
- Maintenance of effect
- Prevention of relapse
 - Kindling?
- Pt acceptability
- Residual symptoms
- Restoring functioning

Which treatment, when, in which order or which combination for which pt?

STAR-D

- Provided more evidence on differential outcomes than some traditional placebo-controlled studies
- Sequential treatment methodology; no placebo
- No remission – progression to 2nd, 3rd, 4th options
- Declining remission with treatment failure typical of chr diseases
- Each new treatment level: ↑ relapse, remission more difficult
- Anxious depressed less likely to respond



Ref: Trivedi
Am J Psych 2006, 2009

KickStarting the Brain

Methodological Challenges of Emerging Technologies

Background

Jill Rasmussen, MD

Regulatory views

William Heetderks, MD, PhD

Discussion

Karl Broich, MD

Electroconvulsive Therapy (ECT): Remaining methodological trial issues for the original brain stimulation technique

Charles Kellner, MD

Discussion

TMS: What has the experience told us?

Jonathan Downar, MD, PhD, FRCPC

Discussion

Break

Intranasal Esketamine: Methodological challenges for a global development program in treatment resistant depression

Jas Singh, MD

Discussion

Statistical Challenges - Novel Technologies

Roseann White, MA

Discussion

Discussant

Paul Holtzheimer, MD

Panel Discussion

Dawn Velligan, PhD

Adjourn meeting

Stephen Marder, MD

5:30 PM End of Day