Surgery as placebo -
the role of placebo trials of surgery

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Angina
Parkinson’s disease
Emphysema
Shoulder pain
Knee pain
Explaining perceived improvement
Polio Rates / Ice Cream Sales 1949

Polio Cases / Ice Cream Sales x100

Month:
- Jan
- Feb
- Mar
- Apr
- May
- Jun
- Jul
- Aug
- Sep
- Oct
- Nov
- Dec
Improvement, but not caused by the surgery

• Natural history

• Regression to the mean

• Concomitant treatment
Perceived improvement, no real improvement

• By the patient
  • The placebo effect

• By the observer
  • Measurement error, reporting bias, confirmation bias, etc.
Therapeutic envelope

Person

Therapeutic environment  Intervention factors
Patient-therapist interaction  Therapist factors
Social factors  Concomitant treatment
Natural course of disease  Regression to the mean

Treated patient
<table>
<thead>
<tr>
<th>Colour</th>
<th>Size</th>
<th>Cost</th>
<th>Number</th>
<th>“Active” placebo</th>
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Building the ideal placebo

- Painful interventions and “procedures”
- Devices
- Confident, enthusiastic, authoritative, important, qualified provider
- Surrounded by symbols of science
Knee arthroscopy

Moseley, NEJM 2002, Sihvonen, NEJM 2013
Why do we still operate

• Belief in effectiveness

• Patient demand?

• “Failure of non-operative treatment”

• Lack of alternatives

• So it’s a placebo – who cares?
Determining effectiveness

• What surgery historically relies on
  • Biologically plausible mechanism
  • Laboratory evidence
  • Observational studies

• What should be used to determine effectiveness
  • The method with the least error
Least biased estimate of true effectiveness:

Adequately powered, multicentre placebo-controlled randomised trials
Knee arthroscopy

Hubbard 1995

Sihvonen 2013
Randomised placebo-controlled trials of surgery: ethical analysis and guidelines

Julian Savulescu,¹ Karolina Wartolowska,² Andy Carr²
Placebos that harm: sham surgery controls in clinical trials

Alex John London Department of Philosophy, Carnegie Mellon University, Pittsburgh PA, USA and Joseph B. Kadane Department of Statistics, Carnegie Mellon University, Pittsburgh PA, USA
Surgery vs best medical therapy (no sham)?

• ‘Because the net therapeutic advantage of an intervention represents a robust measure of its performance’

• The net therapeutic advantage of an intervention represents a robust measure of its *perceived* effectiveness
Criticism:

“Use of placebo in surgical trials may deny participants effective treatment”

“medical practice may harm patients to without benefit”
Ethics of clinical practice vs ethics of research

- Ethics of clinical practice
  - Do not expose patient to risk of harm without possible benefit
  - Placebo not acceptable

Balances risks and benefits on individual patient level

- Ethics of research
  - Find the truth
  - Minimise harm
  - Placebo acceptable

Balances risks and benefits on societal level
Risks: individual vs society

- Individual risk of placebo surgery is overestimated

- Risk to society of continued surgery (of unknown effectiveness) is underestimated
Use of placebo controls in the evaluation of surgery: systematic review
Ethical paradox

• Procedure “X” is developed based on plausibility and lab tests
• Observational data is encouraging
• Procedure becomes common
• Ethics of an RCT:
  • 100-200 patients exposed to 50% chance of no treatment in RCT, but true effectiveness determined
  • Continued practice of procedure X with uncertainty, indefinitely
How much of surgery is effective?

Randomised Trial Support for Orthopaedic Surgical Procedures

Hyeung C. Lim¹*, Sam Adie¹,², Justine M. Naylor¹,²,³, Ian A. Harris¹,²,³
Summary

- Effectiveness of surgery is over-estimated (perception > reality)
- Surgical practice continues without (or against) good evidence
- Placebo trials offer the least biased measure of effectiveness
- Placebo trials are ethical and feasible