Critical Appraisal of Healthcare Research: Observational Studies
Observational Studies

- Cross-sectional
- Cohort
- Case-control
- Case report/series
But, use the Strongest Evidence

- Systematic Reviews and Meta-Analyses
- Randomized Controlled Trials
- Cohort Studies
- Case-Control Studies
- Case Series, Case Reports
- Editorials, Expert Opinion
<table>
<thead>
<tr>
<th>Question Type</th>
<th>Ideal Study Type</th>
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<td>Prospective, blind comparison to a gold standard</td>
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<td>Therapy</td>
<td>RCT &gt; cohort study &gt; case-control &gt; case series</td>
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<td>Prognosis</td>
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<td>Prevention</td>
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Hazardous journeys

Parachute use to prevent death and major trauma related to gravitational challenge: systematic review of randomised controlled trials

Gordon S Smith, JI P Pell

Abstract

Objectives To determine whether parachutes are effective in preventing major trauma related to gravitational challenge.

Design Systematic review of randomised controlled trials.

Data sources Medline, Web of Science, Embase, and the Cochrane Library databases; appropriate internet sites and citation lists.

Study selection Studies showing the effects of using a parachute during free fall.

Main outcome measure Death or major trauma, defined as an injury severity score greater than 15.

Results We were unable to identify any randomised controlled trials of parachute intervention.

Conclusions As with many interventions intended to prevent ill health, the effectiveness of parachutes has not been subjected to rigorous evaluation by using randomised controlled trials. Advocates of evidence-based medicine have criticised the adoption of interventions evaluated by using only observational data. We think that everyone might benefit if the most radical protagonists of evidence-based medicine organised and participated in a double-blind, randomised, placebo-controlled, crossover trial of the parachute.

Introduction

The parachute is used in recreational, voluntary, sectorial, and military settings to reduce the risk of orthopaedic, head, and soft tissue injuries caused by gravitational challenge, typically in the context of jumping from an aircraft. The perception that parachutes are a successful intervention is based largely on anecdotal evidence. Observational data have shown that their use is associated with mortality and morbidity, due to both failure of the intervention and iatrogenic complications. In addition, “natural history” studies of free fall indicate that failure to take or deploy a parachute does not inevitably result in an adverse outcome.

We therefore undertook a systematic review of randomised controlled trials of parachutes.

Methods

Literature search

We conducted the review in accordance with the QUOROM (quality of reporting of meta-analyses) guidelines. We searched for randomised controlled trials of parachute use on Medline, Web of Science, Embase, the Cochrane Library, appropriate internet sites, and citation lists. Search words employed were “parachute” and “risk.” We imposed no language restriction and included any studies that enabled jumping from a height greater than 100 metres.

Accepted intervention was a fabric device, secured by strings to a harness worn by the participant and released (either automatically or manually) during free fall with the purpose of limiting the rate of descent. We excluded studies that had no control group.

Definition of outcomes

The major outcomes studied were death or major trauma, defined as an injury severity score greater than 15.

Meta-analysis

Our statistical approach was to assess outcomes in parachute and control groups by odds ratios and quantified the precision of estimates by 95% confidence intervals. We chose the Mantel-Haenszel test to assess heterogeneity, and sensitivity and subgroup analyses and fixed-effects weighted regression techniques to explore causes of heterogeneity. We selected a funnel plot to assess publication bias visually and Egger’s and Begg’s tests to test it quantitatively. Stata software, version 7.0, was the tool for all statistical analyses.

Department of Obstetrics and Gynaecology, Cambridge University, Cambridge CB2 0QQ. Gordon S Smith (correspondence)

Department of Public Health, Greater Glasgow NHB Board, Glasgow G2 8DU. JI P Pell (consultant)

Correspondence to: G S Smith, gos2@cam.ac.uk

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Value of Observational Research

- Prognosis of disease
- Prevention
- Harm
- Etiology
Evaluating Healthcare Research

- Are the results valid?
- Are the results important?
Selection bias
Information bias
Attrition bias
Selection Bias

- Sample size
- Voluntary participation (prospective)
- Representative sample
  - Demographics
  - Point in disease course
Information Bias

- Self-report (Recall)
- Distant past
- Emotional connection
- Social desirability
- Interviewer error
- Scripting
Methods: Information Bias

- Inconsistent data
  - Missing or incomplete EMR
- Outcome criteria
  - Clearly defined, measurable changes
Confounding Factors

- Factors that directly impact the relationship between exposure and outcome
- Competes with exposure in explaining an outcome
Attrition Bias

• **Loss to follow-up**
  - < 5% = little bias
  - > 20% = serious threat

• **Length of follow-up**
  - Long enough after exposure (prospective)
  - Far enough back (retrospctive)
Evaluating Healthcare Research

Are the results valid?

Are the results important?