

Denis Jobin Tue Jun 12, 2012 <http://groups.yahoo.com/group/XCeval/>
Colleagues,

Sorry for sharing these few thoughts... but had to let go!

A while ago this article has been used in several evaluation circles to discredit RCT as it demonstrate that one does not need RCT to determine effectiveness of a given approach, here use of parachute. I believe it only demonstrated that it discredit its own perpetrators as it is in my view an excellent example of a method driven approach, or path dependence example.

It is a common mistake to use a method to deal with a given evaluation issues because the technic is new or because one is a good econometrician and wishes at all cost to use econometrics or one is a good case study expert and want to do the same.

RCT is wrong methodology to assess this type of problem, like case study is wrong method if one wants to generalize findings to an entire population. Using this example is at best demagogy, at worst obliviousness....

This example, rather entertaining, reminds me that the basic is still too often forgotten by experienced evaluators who get excited by the methods and sees evaluation methodology as a monotheist religion, where only their approach (by demonstrating using rather poor but entertaining rhetoric that the other is flawed) is superior. If it is a religion, at least lets get inspired by the Greeks or Roman where one different god is used for each different problems that one need to face! But the thruth is it, is not a religion.... and what is good today, won t be tomorrow. Its ongoing and endless improvement methods.... and learning....

Since the lauch of the debate about RCT few years ago, and gold or not std and the following greater focus on what quality, rigourouness or impact is or is not, i would believe its - the overall debate (not the positionS) - has been overall positive for the evaluation community....

Cheers - DJ

Hazardous journeys

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

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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 > 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 sector, and military settings to reduce the risk of orthopaedic, head, and soft tissue injury after 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 morbidity and mortality, due to both failure of the intervention^{1 2} and iatrogenic complications.³ 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.⁴ 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.⁵ 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 ‘‘trial.’’ We

imposed no language restriction and included any studies that entailed jumping from a height greater than 100 metres. The 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 15.⁶

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.

Results

Our search strategy did not find any randomised controlled trials of the parachute.

Parachutes reduce the risk of injury after gravitational challenge, but their effectiveness has not been proved with randomised controlled trials
Credit: HULTON/GETTY

Discussion

Evidence based pride and observational prejudice

It is a truth universally acknowledged that a medical intervention justified by observational data must be in want of verification through a randomised controlled trial. Observational studies have been tainted by accusations of data dredging, confounding, and bias.⁷ For example, observational studies showed lower rates of ischaemic heart disease among women using hormone replacement therapy, and these data were interpreted as advocating hormone replacement for healthy women, women with established ischaemic heart disease, and women with risk factors for ischaemic heart disease.⁸ However, randomised controlled trials showed that hormone replacement therapy actually increased the risk of ischaemic heart disease,⁹ indicating that the apparent protective effects seen in observational studies were due to bias. Cases such as this one show that medical interventions based solely on observational data should be carefully scrutinised, and the parachute is no exception.

Natural history of gravitational challenge

The effectiveness of an intervention has to be judged relative to non-intervention. Understanding the natural history of free fall is therefore imperative. If failure to use a parachute were associated with 100% mortality then any survival associated with its use might be considered evidence of effectiveness. However, an adverse outcome after free fall is by no means inevitable. Survival has been reported after gravitation challenges of more than 10 000 metres (33 000 feet).⁴ In addition, the use of parachutes is itself associated with morbidity and mortality.^{1-3, 10} This is in part due to failure of the intervention. However, as with all interventions, parachutes are also associated with iatrogenic

complications.³ Therefore, studies are required to calculate the balance of risks and benefits of parachute use.

The parachute and the healthy cohort effect

One of the major weaknesses of observational data is the possibility of bias, including selection bias and reporting bias, which can be obviated largely by using randomised controlled trials. The relevance to parachute use is that individuals jumping from aircraft without the help of a parachute are likely to have a high prevalence of pre-existing psychiatric morbidity. Individuals who use parachutes are likely to have less psychiatric morbidity and may also differ in key demographic factors, such as income and cigarette use. It follows, therefore, that the apparent protective effect of parachutes may be merely an example of the “healthy cohort” effect. Observational studies typically use multivariate analytical approaches, using maximum likelihood based modelling methods to try to adjust estimates of relative risk for these biases. Distasteful as these statistical adjustments are for the cognoscenti of evidence based medicine, no such analyses exist for assessing the presumed effects of the parachute.

The medicalisation of free fall

It is often said that doctors are interfering monsters obsessed with disease and power, who will not be satisfied until they control every aspect of our lives (*Journal of Social Science*, pick a volume). It might be argued that the pressure exerted on individuals to use parachutes is yet another example of a natural, life enhancing experience being turned into a situation of fear and dependency. The widespread use of the parachute may just be another example of doctors' obsession with disease prevention and their misplaced belief in unproved technology to provide effective protection against occasional adverse events.

What is already known about this topic

Parachutes are widely used to prevent death and major injury after gravitational challenge
Parachute use is associated with adverse effects due to failure of the intervention and iatrogenic injury

Studies of free fall do not show 100% mortality

What this study adds

No randomised controlled trials of parachute use have been undertaken

The basis for parachute use is purely observational, and its apparent efficacy could potentially be explained by a “healthy cohort” effect

Individuals who insist that all interventions need to be validated by a randomised controlled trial need to come down to earth with a bump

Parachutes and the military industrial complex

However sinister doctors may be, there are powers at large that are even more evil. The parachute industry has earned billions of dollars for vast multinational corporations whose profits depend on belief in the efficacy of their product. One would hardly expect these vast commercial concerns to have the bravery to test their product in the setting of a randomised controlled trial. Moreover, industry sponsored trials are more likely to conclude in favour of their commercial product,¹¹ and it is unclear whether the results of such industry sponsored trials are reliable.

A call to (broken) arms

Only two options exist. The first is that we accept that, under exceptional circumstances, common sense might be applied when considering the potential risks and benefits of interventions. The second is that we continue our quest for the holy grail of exclusively evidence based interventions and preclude parachute use outside the context of a properly conducted trial. The dependency we have created in our population may make recruitment of the unenlightened masses to such a trial difficult. If so, we feel assured that those who

advocate evidence based medicine and criticise use of interventions that lack an evidence base will not hesitate to demonstrate their commitment by volunteering for a double blind, randomised, placebo controlled, crossover trial.

Footnotes

- Contributors GCSS had the original idea. JPP tried to talk him out of it. JPP did the first literature search but GCSS lost it. GCSS drafted the manuscript but JPP deleted all the best jokes. GCSS is the guarantor, and JPP says it serves him right.
- Funding None.
- Competing interests None declared.
- Ethical approval Not required

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