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Should we accept a higher risk of type I errors in some trials?

Jens Laigaard

Copenhagen, Denmark

E-mail: xrw218@alumni.ku.dk

Keywords: clinical trial; power analysis; sample size; statistics; type I error; type II error

Editor—The well-performed sample size calculation is key when conducting a properly powered trial. In the sample size calculation, we make considerations about the least clinically important difference between the groups to be compared, that is effect size (δ). We choose the risk of type I (α) and type II (β) errors and make assumptions on the variability (σ) of the outcome measure in each group. These factors affect the sample size and thereby the cost of the trial. Sample sizes are relatively small in trials searching for large differences, accepting high risk of false-positive and false-negative findings. On the contrary, trials searching for small differences, with low risk of false-positive and false-negative findings, require larger sample sizes.

The most frequently used α value is 0.05. Accordingly, the risk of finding a statistically significant difference between groups in the sample that does not exist in the population is 5% (when ignoring Bayesian thinking). The statistical power is often 0.80 or 0.90. A power of 0.80 results in 20% risk for acceptance of a false null hypothesis – that is a false negative.

So, why do we accept a relatively higher risk of extrapolating non-existing differences to the population than of not finding existing differences to the population? For treatments that in some way require a large amount of resources, we would rather risk not introducing a beneficial treatment, than introduce an indifferent or potentially harmful treatment. This is the 'first, do not harm' principle. However, although this is perfectly rational when testing interventions against placebo, current clinical practice, a cheaper treatment, a lower dose or likewise, sometimes this is not the case.

Sometimes we compare interventions that are equal *a priori*, for example requiring equal resources and with equal risk of side-effects. In these cases, false positives (e.g. finding differences that do not exist) are not worse than false negatives (e.g. not finding differences that do exist). In other words, when we do not have a favourite between intervention arms, we should focus on minimising the overall risk of error. In trials where the intervention arms seem equal *a priori*, we should accept equal risk of type I and type II errors to minimise the combined risk of error for a given sample size.

One example is high *vs* low arterial oxygen fraction in critically ill patients as tested in the Handling Oxygenation Targets in the Intensive Care Unit (HOT-ICU) trial.[1] The trial tests whether a target of 8 or 12 kPa oxygen in arterial blood gas samples is preferable in critically ill hypoxaemic patients. With either oxygenation target, the same amount of time and effort is needed. Also, it is unlikely that the volume of oxygen used will have an impact on the health economic analysis. In this trial, an α of 0.05 and a β of 0.10 was chosen for the primary outcome of 90 day mortality with a sample size of 2928 patients to find a 20% relative risk reduction between groups. In the HOT-ICU trial, if they instead set the α at 0.075, a power of 0.93 could be maintained, while keeping the same sample size. This lowers the total risk of error from 15% to 14.5%. A small

difference, to be sure, but to make the most of time-consuming and costly trials we must consider all options in optimising the value of our results.

Declarations of interest

The author declares that they have no conflicts of interest.

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Anaesthetic management of subcutaneous abscesses: current status

Theodore Poulton, Samuel P. Hogston, William S. Bolton, Joshua R. Burke* and David G. Jayne

Leeds, UK

*Corresponding author. E-mail: Joshburke@doctors.org.uk

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Editor—Subcutaneous abscesses are superficial pus-filled cavities that are often caused by an acute bacterial infection and can occur anywhere in the skin.[1] Conventional incision and drainage (I&D) remains the primary choice of procedure in the UK, with breakdown of loculations, irrigation, packing, and healing via secondary intention. However, there remains variation in practice as to the anaesthetic choice between topical, local, regional, and general anaesthesia. I&D requires adequate anaesthesia to minimise pain and allow for tolerable manipulation of tissues to optimise: (i) drainage and (ii) aesthetic outcome. The choice of anaesthetic method is likely made as a combination of patient, surgeon, or anaesthetist preference. To date, there are no guidelines to aid anaesthetic choice in the management of patients with subcutaneous abscesses.

We reviewed the literature examining anaesthetic choice for subcutaneous abscess management, highlighting studies comparing anaesthetic methods, to provide an overview of the current status. The National Institute for Health and Care Excellence Evidence Service's Healthcare Database Advanced Search was used to search the following databases and identify suitable records: PubMed, MEDLINE (1945–present), and EMBASE (1974–present), for titles and abstracts specifically relating to both abscesses and anaesthetic. References of full text manuscripts were screened for any additional articles. Screened articles were considered eligible if they both (i) involved the acute management of subcutaneous abscesses and (ii) investigated the effect of anaesthesia on abscess management. The initial search returned 1145 publications. After removal of duplicates, 607 publications remained. Of the screened publications, six articles met the inclusion criteria and were included in the final analysis. Because of the study heterogeneity, a narrative synthesis was conducted for this correspondence (Table 1).

Topical anaesthesia and spontaneous abscess drainage

There is evidence to suggest that topical anaesthetic cream is associated with an increase in spontaneous abscess rupture.[2,3] In a small study (n=41), spontaneous rupture occurred in 51% of patients who received lidocaine/prilocaine cream applied to the abscess for an average of 90 min compared with controls.[2] A larger observational study compared paediatric patients receiving topical lidocaine (n=110) *vs* control (n=59) before I&D reported a 24% (95% confidence interval: 14–32) increase in spontaneous rupture in the topical anaesthetic group.[3]

Topical vs local anaesthesia

A prospective, doubled-blinded RCT was carried out in an adult emergency department in the USA that compared injectable lidocaine with transdermal lidocaine/tetracaine patches for abscess I&D.[4] The study reported a similar level of pain between the injected lidocaine 1% group and lidocaine/tetracaine patch group. No statistically significant difference