

Received Date : 22-Jun-2016

Revised Date : 22-Jun-2016

Accepted Date : 25-Jun-2016

Article type : Editorial

The translational value of chart reviews and the need for trials

In this issue we publish the results from a retrospective cohort study examining the impact of preoperative underbody forced air warming on clinical outcomes in children who underwent spinal deformity surgery (1). The authors compared outcomes before and after pre-warming was introduced at British Columbia's Children's Hospital in 2011, and found evidence for an association between pre-warming and reduced allogeneic red blood cell transfusion. Therefore, should we now pre-warm our children?

When considering whether or not to change practice a clinician considers a range of factors, including the theoretical likelihood that the intervention should work based on our understanding of physiology etc, and the quality of the *clinical* studies in terms of likely bias or confounding, the strength of the association (how big a difference was seen), and the degree of certainty or precision (often expressed in terms of a P value or width of the 95% confidence interval). It is certainly biologically plausible that pre-warming would reduce hypothermia and hence the need for transfusion, but does this study provide compelling clinical evidence? The answer is a clear no. It is a retrospective observational cohort study showing an association but we cannot assume there is cause and effect. Clinical practice likely changed over time and these various unmeasurable changes could be the reason for the observed reduction in transfusion over the time period of this study. This is a clear case where the observed association may well be due to confounding. Confounding is when other extrinsic factors have an impact on both the likelihood of exposure and the likelihood of the outcome, causing an apparent but non-causative link between exposure and outcome. While the authors adjust for some potential cofounders in their analysis, they acknowledge the inability to take into consideration other significant cofounders. Also, as for all such observational studies there may be confounding factors which are simply unknown. If this study (and other similar purely

This is the author manuscript accepted for publication and has undergone full peer review but has not been through the copyediting, typesetting, pagination and proofreading process, which may lead to differences between this version and the [Version of Record](#). Please cite this article as [doi: 10.1111/pan.12976](https://doi.org/10.1111/pan.12976)

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observational studies) provides only weak evidence which, by itself is probably not sufficiently compelling to change practice, then why publish it?

Firstly, while the evidence is weak it still provides *some* evidence, which may be the best there is, or given other evidence it may tip the balance to changing practice. The strongest clinical evidence comes from high quality adequately powered clinical trials. Well-designed trials are regarded as the strongest evidence of causality because randomization is the most effective way to reduce confounding. The value of these trials cannot be overstated. However, experimental trials are not always necessary; the rationale justifying the intervention may be sufficient and the chances of confounding negligible (e.g. do parachutes prevent lethal outcomes when leaping from a great height). In other situations, trials are practically impossible to do (for example in very rare diseases, or rare events where the numbers needed to adequately power the study would be unattainable). Observational cohort studies and retrospective chart reviews are quicker, easier and cheaper than trials. Also the risk of known confounding can be reduced by variety of adjustment strategies. While not conclusive, well designed and adequately powered observational studies can still provide some useful evidence which a clinician can add to all the other factors that influence their decision as to whether or not to change practice. The risk is that if other evidence is weak, and clinicians may not fully appreciate the limitations then practice may change for the worse. Children may be harmed or health dollars wasted.

There is a second reason for publishing observational studies. While the evidence *per se* should not change practice, it may provide the impetus for further research. This is sometimes known as “hypothesis generating”. Well performed, adequately powered trials are expensive and resource intensive. They usually require external funding and sources of such funding are increasingly competitive. They are a powerful and expensive tool that can only be used selectively. One prerequisite to justify a trial is some evidence from observational studies for an association between the intervention and a better outcome. If there is no preliminary evidence for such an association then it is unlikely that a trial will find evidence for causation; and hence it is unlikely that the trial will be funded.

Thus when you consider the translational value of the pre-warming paper, it is not in its ability to change practice. The translational value lies in its merit to provide the rationale for a properly designed and conducted trial which will then provide the best evidence for changing practice, or not. Any takers?

1. Görges M, West NC, Cheung W, Zhou G, Miyajiri F, Whyte SD. Preoperative warming and undesired surgical and anesthesia outcomes in pediatric spinal surgery—a retrospective cohort study. *Pediatr Anesth* 2016 DOI: 10.1111/pan.12939

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