Anesthetists test scale that measures risk of harm from invasive research placebos

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A scale developed to measure the potential harm caused by invasive placebos in local anaesthesia research has been successfully tested by a group of 43 independent clinicians, according to research published in the April issue of *Anaesthesia*.

The consultant anaesthetists were asked to assess the risk of harm posed by control group interventions described in ten published clinical anaesthesia studies using the Serious Harm and Morbidity (SHAM) scale.

There was substantial agreement between the 22 consultants who were given clinical examples to illustrate the scale and moderate agreement between the 21 consultants who were not provided with clinical examples to inform their decisions.

Agreement was also particularly high among consultants holding academic posts and the authors suggest this may reflect their greater familiarity with assessing medical research.

The anaesthetists also agreed with the scores allocated to the studies by the scale's developers in 68% of cases.

The details of the SHAM scale, which was created by doctors in Adelaide, Australia, were first published in Anaesthesia in February 2011. This paper showed that a large number of clinical studies employed highly invasive placebos.

"Such practices appear to contravene the World Medical Association's Declaration of Helsinki on Ethical Principles for Medical Research Including Human Subjects" explains study lead Dr Allan Cyna, a consultant anaesthetist from the Women's and Children's Hospital in North Adelaide and a Clinical Senior Lecturer at the the University of Adelaide.

"The Declaration, first published in 1964 and last amended in 2008, states that 'patients who receive placebo or no treatment will not be subject to any risk of serious or irreversible harm'.

"More than half of the research papers we looked at for the scale development study, published in 2011, subjected control group patients to risks of moderate or major harm and ill health without apparently considering the use of a less invasive placebo."

The initial 2011 study showed how the authors tested the zero to four-point scale by grading 59 studies. This showed that 31 studies covering 913 patients represented moderate or major risks, including six studies involving 183 children.

For the latest study, the 43 consultant anaesthetists, who were not involved in the development of SHAM, tested the scale by grading ten published clinical papers chosen at random from the 59 used in the original study. Their results were then analysed using Fleiss kappa, which assesses the reliability of agreement between a fixed number of raters using a scale of zero (no agreement) to 1.0 (total agreement).

Overall agreement between the assessors was 0.50 and the score was 0.60 when it came to assessors agreeing whether studies were high risk or low risk. When anaesthetists were given clinical examples to illustrate the scale, the scores rose even higher and they were much more likely to agree with each other than those who were not given examples (0.76

versus 0.45). Agreement was also significantly higher among those in academic posts (0.60) than those who did not hold such posts (0.46).

Explaining the rationale behind the development of the scale, Dr Cyna says: "Placebos, such as sugar pills or saline injections, are frequently used in research to assess new techniques or drugs. Because they contain no active ingredients they provide a useful control. However in the context of a placebo local anaesthetic control, the technique itself may risk complications that could be avoided with a less invasive alternative without reducing scientific validity."

"The results of our latest study suggest that the SHAM scale can be successfully used to grade the severity of potential complications of placebo-controlled interventions in local anaesthesia research and this represents a first step towards the score's validation" concludes co-author and senior registrar Dr James Jarman.

"The SHAM scale draws attention to the potential for harm and it is important to point out that actual harm is rare in anaesthesia research. We believe that if clinicians involved in anaesthesia research were to use the SHAM scale to assess the potential harm caused by their placebo control, it could lead to them choosing less invasive options. Our study emphasises that in local anaesthesia research we should be using the least invasive placebo that is consistent with maintaining scientific rigour, so as to make research as safe as possible."

More information: Anaesthetists' risk assessment of placebo nerve block studies using the SHAM (Serious Harm and Morbidity) scale. Jarman et al. Anaesthesia. 67, pp361-366. (April 2012). doi:10.1111/j.1365-2044.2011.06998.x

The development of the scale is discussed in: Use of invasive placebos in research on local anaesthetic interventions. McGuirk et al. Anaesthesia.

66, pp84-91. (February 2011). doi:10.1111/j.1365-2044.2010.06560.x