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GUEST EDITORIAL

More to the paper on 'Homeopathy in Sepsis in ICU' than meets the eye

Frass *et al* are to be congratulated on an excellent piece of work on the role of homeopathy in critically ill patients.[1] It is a pleasant surprise to read the use of homeopathy in severe, acute illness. Homeopathy is more often associated with chronic illness and with intractable conditions where other treatments are limited by side effects and/or poor efficacy. Of course, earlier in its history (perhaps as late as mid-20th century) homeopathy had numerous examples of benefit in life-threatening illnesses. Could this paper mark a revival of homeopathy in this area?

I admire the authors for taking a bold step, also for persuading the ICU medical staff and the ethics committee to support a trial of homeopathy in adult septic shock. I am intrigued by (and a little jealous of) this achievement! Like all important papers, this one sparks many thoughts, including:

- The role of randomised control trial in homeopathy (the issue of simplicity vs complexity).
- The nature of information provided by the results of a randomised controlled trial, and not just in relation to homeopathy.
- Attempting to quantify treatment effects and their importance.
- The apparent lack of antidoting and interference by potent drugs on homeopathy.

Classical homeopathy is a complex intervention involving multiple components. It has therefore been argued that the double-blind randomised control trial (DBRCT) method poses several methodological difficulties when applied to homeopathic practice.[2] The complexity arises from the inherent nature of homeopathic history taking, individual practitioners, knowledge and experience, accuracy of prescription and often the need for several medicines in sequence to effect a successful outcome. In this study, however, the homeopathic intervention was simplified, apparently to a single homeopathic review within 48 h of enrolment in the study and the same medicine repeated every 12 h.

Where a therapeutic intervention has been simplified to essentially one step or task, the DBRCT method of assessing efficacy is a powerful tool. One of its main strength is that the conclusions drawn from trials using such methodology can be robust. But mainstream practitioners have rightly been reluctant to accept the limitations of DBRCTs when applied to complex interventions. A good example was the reporting of a multi-centre trial of caesarean section vs vaginal delivery for the management of breech presentation, which concluded that vaginal delivery was not as safe as caesarean section.[3]

A subsequent review published in the BMJ criticised the conclusion because the complexity of 'safe vaginal delivery' was studied as if it were a simple one-step intervention.[4] Whereas in reality the intervention is determined by the experience of the clinical team, the number of vaginal breech deliveries performed in each participating unit, the method and style of foetal monitoring and the confidence in managing breech delivery, to name but a few. The sweeping conclusion that caesarean section is safer than vaginal delivery was criticised as an over simplification. The challenge remains to find the most appropriate tool for studying 'complex' homeopathy. But for 'simple' homeopathy the DBRCT has its uses. Note that here 'complex' refers to the nature of the intervention, not the homeopathic medicine.

The types of conclusions that can be drawn from a DBRCT

In order to draw robust and safe conclusions the trial itself must be well designed and conducted. The outcomes must be clinical relevant and accepted. Frass et al did a wonderful job of ensuring the methodology is sound and so the conclusions are likely to be reliable. Please note my careful choice of words '*likely to be reliable*'. This is the nature of conclusions that the randomised control trial method allows us. The difference in survival at 180 days of 75.8% in the homeopathy group compared to 50% in the placebo group has a *P*-value of 0.043. This means that there is a 1 in 23 probability that the results obtained are purely by chance. The only way to be more certain of homeopathic effect in the intensive care unit would be to repeat the trial, ideally in a different setting with at least the same number, if not more, patients enrolled.

In order to repeat the trial one would need more information on the methodology and this is my only criticism of the paper. The methods section does not give vital information on the homeopathic methodology used. For instance what kind of history did the

homeopaths take? What kind of prescribing strategy did they use? Were different homeopathic medicines used after the first or second doses and how long were the homeopathic medicines given?

Size of treatment effect

The DBRCT method allows us to quantify efficacy of an intervention, but this requires the results to be reported in a format that includes 'numbers needed to treat' (NNT). The NNT for this study is small at 1 in 4 (95% CI 2–29). One life saved for every 4 patients treated! In comparison the most important recent conventional advance in septic shock is recombinant-activated protein C which has a NNT of 1 life saved for every 16 patients treated with a risk of a bleeding event of 1 in 66.[5]

Lack of interference of homeopathic action by allopathic treatment

In this study homeopathy seemed to be effective despite the myriad medications used in the intensive care setting, including intravenous hydrocortisone. This really questions our understanding of antidoting and could throw the cat among the pigeons, especially among those who have a dogmatic approach to possible interference by conventional treatments. (Personally, I have always wondered what all the fuss was about when homeopathy benefits cows even if added to their feed. In future I might not worry so much about a little coffee when advising my patients!)

My personal experience of homeopathy in intensive care is limited to only 2 patients in the Paediatric Intensive Care Unit (PICU) at Great Ormond Street Hospital for Sick Children. Both did better than expected and were discharged from PICU. I prescribed on a pathological basis, eg *Apis* for severe ascites, *Carbo veg* because of blue, cold peripheries. I am tempted to knock on a few doors again, after reading this inspiring paper. This subject needs more study, especially in children. The practicalities are a little daunting however, as the number of severe sepsis patients in 2004 was between 40–60 in the six largest PICUs in the UK.[6] But where there is a will .....

References

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