The revised position papers on gastric decontamination

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The AACT/EAPCCT Position Statements published between 1997 and 19991–5 were a major attempt to summarise the evidence on gastrointestinal decontamination and to develop recommendations based on this evidence. Launched with some fanfare, they were an important landmark in cooperation between European and North American societies and their conclusions have been widely cited. Seven years later, the first updated versions of the position statements are now being published.6–8 Perhaps it is time for the clinical toxicology community to take stock of what has happened in research on gastrointestinal decontamination since these position statements were published, and since they concluded that there was insufficient clinical trial evidence to support the use of any form of gastrointestinal decontamination in any situation.

The strongest recommendations for changes in practice were directed against ipecac, gastric lavage, and cathartics. The use of activated charcoal more than one hour after ingestion was also strongly questioned. Undoubtedly, there have been substantial changes in practice over the last decade and the position statements have provided the necessary collegiate support for this to occur.

However, implications about the need for further research that should have been drawn from these documents have not lead to an increase in high quality clinical research in this area. On the contrary, in the last seven years we believe that only three controlled clinical trials of gastrointestinal decontamination have been published. One of these has been published only in abstract,9 one was of a twelve year old trial 10 that had flaws in design and analysis,11 and one addressed the very specific question of the role of MDAC in yellow oleander poisoning.12 Therefore, unless a doctor treats oleander poisoning, the published clinical evidence has not progressed over the last seven years. The three updates published to date conclude their abstracts with ‘A review of the literature since the preparation of the 1997 ___ Position Statement revealed no new evidence that would require a revision of the conclusions of that Statement.’

While not intended as such, this is a sad indictment on the progress of research in clinical toxicology, because the published evidence is very weak indeed. The methodology of the clinical trials reviewed was poor and should not preclude anyone from conducting a better designed study to address the same hypotheses. Future trials will need to pay closer attention in particular to ensuring random allocation, allocation concealment, and avoidance of selection or outcome bias.

For example, the 2004 AACT/EAPCCT Position Paper on the use of ipecac syrup6 described five studies as randomized controlled trials (RCTs). In a two arm trial, randomisation ensures that there is equal probability of a patient being allocated to either arm.13 Allocation concealment then prevents prediction of allocation.14 Systematic biases occur when allocation is not concealed – if a doctor is able to predict the allocation, then s/
he may decide not to recruit a patient if they would get an intervention the doctor does not favour. Methods to ensure this does not happen are embedded in current standards for clinical trials.

Four of the cited studies used alternate day allocation or pseudo randomisation. Allocation was not ‘randomized’ because there was not an equal probability of allocation to either arm – if the patient arrived on a Wednesday, according to the protocol, s/he could only have been allocated one specific intervention.

There was also no allocation concealment – the enrolling doctor knew what the patient was going to receive from the day of presentation. If the doctor’s non favoured intervention was indicated, s/he could have not recruited the patient or (if late in the day) delayed the patient in the waiting room until midnight had passed and the other intervention became available. Such practices have been recorded in many studies, and therefore pseudo-randomised studies are considered weaker evidence than RCTs.

Saetta’s study did not even pseudo-randomise patients. The control patients in this study were specifically selected because they were considered to be either too well for gastric decontamination or presenting too late for it to have an effect. The surrogate primary outcome selected was also biased against the use of ipecac as the vomited tablets were excluded from statistical consideration in measuring the effectiveness of ipecac in preventing tablet movement into the small bowel. This systematic bias in selection of control patients and outcome assessment prevents any meaningful conclusion being drawn from this study.

Similar problems of quasi-random allocation without concealment beset most studies on other methods of gastric decontamination and many have other design flaws. In order for the field to progress, it is important that the clinical studies that have been done are critically and rigorously evaluated (particularly in authoritative position papers).

We sincerely commend the authors of these studies for providing the best available evidence, but we also need to critique their studies to highlight the problems and move the clinical toxicology community to provide more and better research evidence. The evidence for many interventions in clinical toxicology is weak. It will only improve if we make the first step of recognising that we have a problem.

References


