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New Junctures in Research, Evaluation and Management Pave the Path of Improvement

Professor Benoit Vallet, Chair for the Department of Anaesthesiology and Intensive Care Medicine at the University Hospital of Lille, France has played a great influence in his fields of professionalism over the years, with his current participating role in the steering committees for the Age of Blood Evaluation (ABLE) randomised controlled trial and European surgical outcomes (EuSOS) study just providing part of the grand picture. With the realms of critical care and anaesthesia continually evolving, whether via enhancements in education and standards, new research findings or technological developments, Managing Editor Marianna Keen asked Prof. Vallet to share his thoughts on the most influential recent achievements and potential areas of focus for future advancement.

You Have Suggested That Quality Improvement Programmes Could Help to Resolve Uncertainty in Perioperative Haemodynamic Therapy. How do You Think this Technique of Evaluating New Clinical Strategies is Better Than Other Research Methods?

Quality improvement research programmes have emerged over the past five years and allow the evaluation of new clinical strategies in real life conditions (Pronovost et al. 2006). When the quality improvement programmes are applied in routine, the control results reflect the real quality level in the hospital and not only the level of a test group. Indeed, when participating in a study, caregivers might ameliorate their behaviour and thus impede the extrapolation of randomised controlled trial (RCT) results. Moreover, a blind design is not applicable in the context of perioperative monitoring.

A very recent survey showed that the vast majority of anaesthetists do not follow perioperative haemodynamic protocols during high-risk surgery (Cannesson et al. 2011). This would illustrate very well that uncertainty regarding the value of perioperative hemodynamic therapy to improve outcome remains very high (McDonald and Pearse 2011). Available evidence from several RCTs should resolve this uncertainty, but they could be considered not large enough (McDonald and Pearse 2011). Furthermore, manpower would become an important limitation when implementing a new treatment protocol in daily practice in the real world, whereas it is rarely an issue when conducting a drug clinical trial.

We are not convinced, therefore, that large RCTs can solve our uncertainty (Michard, Cannesson and Vallet 2011).

In What Ways have Research and Evaluation Methods in the Fields of Critical Care and Anaesthesia Changed in Recent Years?

In recent years, well conducted clinical research in intensive care has very often ended up with contradictory results, if not opposite results. Large positive RCTs were too frequently followed by negative ones, destroying hopes for patients as well as clinical guidelines for doctors. Clinical trials are often biased; their results do not pertain to real life practice. Research that is overly protocolised may include such a broad case mix of patients that they are not similar to those we have to treat on a routine basis. Sometimes the results from the studies are such that I cannot interpret them for my practice. Other times, clinical trials may not be biased, but recommendations derived from observed results were impossible for my medical staff to translate. For example, manpower may be far larger in the clinical trial than in my ICU or operating room.

One may wonder, therefore, whether monitoring technologies need be evaluated in terms of their effect on outcome of critically ill patients. That is a difficult question to answer. Most administrators will expect to have outcome data on any new and potentially expensive technology before purchasing it. However, this approach may well delay the implementation of useful technologies in the critical care environment, since it is more likely that initial studies, if well conducted, present the worst case scenario (no impact on outcome) (Council BoHCSNR 2002). As an example, the pulse oximeter has been indicated to have no impact on patient outcome (Moller et al. 1993). In the same vein, the aviation industry, which is based on pure science, has never waited for evidence-based data before implementing new technologies (monitors, auto pilot, simulation) to the field. Meanwhile, the medical community is still wondering whether pulse oximetry can improve outcome.

What do You Believe to be the Hottest Topics in the World of Critical Care and Anaesthesia at the Moment?

Non-invasiveness, data management and clinical decision support are the hottest topics in the world of perioperative medicine, along with that of the rising continuum of care between the OR and the ICU. One may increasingly observe that the technology used in both these settings is the same: this pertains to ventilators and ventilatory modes; general monitoring devices, including sedation and pain assist monitoring and delivering systems; and more specific haemodynamic monitoring technologies. From the early nineties, non-invasiveness has been considered a key factor for success in the development of monitoring in the OR; today this appears to be the case in the ICU as well. Patients are less sedated, more prone to be non-invasively ventilated, and as a consequence are more likely to be non-invasively monitored.

One may also observe that in hospital rooms, a lot of the computerised equipment used records data before, during and after surgery (drug delivery, vital signs, physician observations). This equipment produces billions of measurements each day. These data are stored in huge databases and may be integrated with other facts from the Hospital Information System (patient and hospital stay information). That is why data management is certainly one of the hottest topics in critical care and anaesthesia at present.

Which do You Believe to be Your Most Significant Recent Research Developments?

Meta-analyses of these small RCTs provide evidence for supporting perioperative haemodynamic therapy. Recently, Marik et al. conducted a meta-analysis evaluating the ability of pulse pressure variation (PPV) to predict fluid responsiveness (Marik et al. 2009). Their study assessed the range of uncertainty of the estimated best cutoff value. It would be fair to emphasise that meta-analyses of diagnostic tools and cutoff values are not as powerful as they are for RCTs. There are four reasons for this — One: individual studies can considerably vary the threshold used, the population under study, and the measurement of the variable or reference standard; two: the choice of recruitment strategy can also affect the assessment; three: the statistical techniques used to aggregate the results of diagnostic tool studies differ from those of RCTs; and four: the meta-analysis of diagnostic studies requires consideration of two index measures— sensitivity and specificity—as opposed to a single index in the meta-analysis of an RCT.

In order to solve these difficulties, I was part of a team that conducted the first study to test the application of the grey zone (GZ) concept to PPV for the prediction of fluid responsiveness, and to do so in a large sample (Cannesson et al 2011).

The Types of Fluids to Administer to Specific Cases is a Matter That is Highly Debated, as is the Measurement of Fluid Responsiveness. What Impact are Grey Zones Having on the Decision Process of Administering Fluids?

The GZ approach has been proposed to avoid the “black-or-white” decision of the receiver operating characteristic (ROC) curve approach. The ROC curve approach often does not fit the reality of clinical or screening practice. The GZ approach proposes two cutoffs that constitute the border of the GZs. One excludes the diagnosis (predicting no fluid responsiveness), and one includes the diagnosis (predicting fluid responsiveness). Intermediate values in the GZ mean a prediction is not precise enough for diagnostic decision. The GZ approach applied to PPV for predicting fluid responsiveness in mechanically ventilated patients during general anaesthesia identifies a range of PPV values for which fluid responsiveness cannot be reliably predicted. This occurred in our study between nine and 13 percent (Cannesson et al. 2011). Such PPV values may be seen in approximately 25 percent of patients.

The benefit-risk balance of fluid administration may vary between patients. Using the GZ approach instead of a single-threshold value for conducting goal-directed therapy may improve fluid management by ensuring minimisation of the explicit cost ratio (to avoid fluid restriction when fluid administration should be considered and to avoid fluid administration when restriction should be considered). Very interestingly, changes in the cost ratio of volume expansion moderately affected the GZ limits.

By administering cardiac output maximisation with small bolus infusion (100ml), or by considering absolute changes in PPV (dPPV) according to time, we should be able to define fluid response within the limits of the GZ. This would combine cardiac output maximisation and dynamic indicator minimisation.

What Research Projects do You Currently Have Underway?

We are currently working on a data mining project, with the aim of establishing anaesthesia quality rules.

The University Hospital of Lille deals with about 50,000 anaesthesia procedures per year. The information related to these procedures— from pre-anaesthetic consultation to the recovery room—are collected and consolidated into the Anaesthesia Data Management System and stored in a shared database for all the anaesthesia units. We are building a data warehouse, with anaesthesia data coming from two different sources: the Anaesthesia Data Management System and the Hospital Information System. Thanks to this data warehouse and statistical analysis, we should be able to make a connection with respect to anaesthesia quality rules and patient outcomes. After validation of these rules, we will consider the development and implementation of a computerised decision support system.

This project should also allow us to reach other targets. For example, the development of dashboards will give us a better view of anaesthetic activity in the hospital (drugs consumption, anaesthesia quality, OR occupancy, and so on). Moreover, the relationship between the Anaesthesia Data Management System and the Hospital Information System will help us to implement identity-vigilance controls. This information consolidation and interpretation will allow us to develop our own quality improvement research programme.

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