Commentary

Validation of continuous cardiac output technologies: consensus still awaited

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See related research by Marque *et al*., http://ccforum.com/content/13/3/R73

Abstract

An ability to measure cardiac output in a continuous and non-invasive fashion is eagerly awaited in the field of intensive care practice. Modern technologies purport to be able to do this, but the design of studies that validate the manufacturers' claims is by no means straightforward. It is imperative that the scientific community describes and agrees on a set of principles that will enable us to design and then review and assess future validation studies, so that new technologies can be fairly assessed and compared with their competitors.

In recent years there has been a move toward technologies that monitor cardiac output continuously and in a less invasive fashion than the pulmonary artery catheter [1-3]. This has brought many new challenges to the fore that perhaps had not previously been considered. One of these challenges pertains to how we validate the accuracy and precision, or in other words the utility, of the new devices. Difficulty arises because previous studies assessing intermittent techniques compared the measurement of cardiac output at a discrete time point against a reference 'gold standard'. The statistical methodologies used to analyze these data are well described [4,5]. This is not the case for studies assessing continuous monitoring of cardiac output.

Marque and colleagues [1] present an interesting study that highlights some of these issues. In their study they demonstrate that Bioreactance (Cheetah Medical Inc., Tel Aviv, Israel) can track changes in cardiac output in patients after cardiac surgery and conclude that its performance is similar to that of the Vigileo version 1.01 (Edwards Lifesciences, Irvine, CA, USA). In addition they describe a methodology for assessing continuous data against a 'reference' technique that tracks the same variable. Bioreactance is a relatively new method for monitoring cardiac output; it is based on the principle that the frequency of changes in aortic volume with the cardiac cycle can be detected by alternating electrical signals across the thorax. If this were to work then it would be an almost completely non-invasive method for monitoring changes in cardiac output.

This statistical analysis deserves some attention. The authors correctly suggest that it is more important for continuous data to track changes accurately than it is for them to be precise measurements of the underlying variable. Indeed, this is how they are used in clinical practice. It is important to understand, however, that the absolute value must also be validated; otherwise the tool may be used inappropriately. This requires intermittent measurements that can be compared against a recognized reference. In most cases this would be intermittent thermodilution from the pulmonary artery catheter. Without this the monitor may be shown to track changes accurately but may not be a reliable measurement of cardiac output. For instance if the underlying cardiac output was 5 l/minute and the new monitor described it as 1 l/minute, then even if it were able to track changes accurately it could be used inappropriately, with detrimental consequences for patient management. A relevant analogy for this would be the validation of altimeters in the aviation industry. For obvious reasons an altimeter must be able to detect changes in altitude reliably, but we would be extremely concerned if it were unable to measure the absolute value accurately!

In their study, Marque and colleagues [1] used two reference technologies as comparators for Bioreactance. These consist of continuous cardiac output from the pulmonary artery catheter (Vigilance; Edwards Lifesciences) and also from pulse pressure analysis by the Vigileo (software algorithm version 1.01). Because of the inability of the Vigilance system to track changes in real time (it calculates time averages over an approximate 10-minute moving window), the Vigileo was used as the main reference. This is perhaps unfortunate in view of the fact that many authors have described limitations of this software version in monitoring cardiac output; for

instance, Mayer and coworkers [6] reported percentage errors up to 46% and de Waal and colleagues [7] up to 33% in comparison with the pulmonary artery catheter. Newer versions have been reported to be more accurate and precise [8,9], but more robust validation data are still awaited. Until such data become available, the Vigileo remains a strange choice for a reference tool in a validation study. Despite these limitations, in their evaluation of Bioreactance Marque and colleagues [1] describe some exciting results for this new non-invasive technique. We would advocate caution in extrapolating these results to clinical practice until they have been repeated against more reliable references and in other patient groups. If the technique is proved to work in the patients in whom it will inevitably be used, then this technology will be a major advancement in our haemodynamic monitoring abilities.

What becomes abundantly clear from this paper, as well as many others on a similar subject, is that we have no clear mechanism for reporting data from validation studies of continuous measurement techniques. This heterogeneity limits our ability to generalize data and confuses the readers. This paper takes us a step forward in interpreting the data, but there is an urgent need for the scientific community to come together and develop a consensus on how these studies should be designed, reported and presented.

Competing interests

AR has lectured for LiDCO and acted in the past as a consultant for Edwards Lifesciences. He is on the advisory board of Cheetah Medical.

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