Evaluation of cardiac output monitoring devices: clarity or confusion?

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This issue of the Journal features a study by Chan and colleagues (page 309) comparing measurement of cardiac output with a non-invasive continuous wave Doppler device versus the pulmonary artery catheter (PAC). This study joins a multitude of other evaluations of cardiac output monitoring devices. The two questions implicit in these evaluations are: “What is the new device evaluated against?” and “How close is good enough?”

Thermodilution via the PAC is generally regarded as the clinical “gold” standard against which newer devices are evaluated. This appears logical, as its use is well accepted and widespread. If the new method agrees sufficiently with the established one, then it may replace it. The difficulty in evaluating cardiac output monitoring devices is that the agreement is not so unequivocally complete as to be uniformly convincing. This is evidenced by the varied and inconsistent adoption of the newer methods by clinicians.

Several reasons account for this difficulty. Firstly, we need to recognise that, in the measurement of cardiac output, the true value remains unknown. This is in contrast to calibration in, for example, engineering, where known quantities are measured by a new method, and the results are compared with the known true values. Thermodilution via the PAC has become the default clinical “gold” standard because it was the first method that was easy and feasible to perform at the bedside. However, the literature is full of studies on its lack of absolute accuracy and reproducibility. Over time and with familiarity, we have learnt to use the PAC to yield results that are as accurate and reproducible as possible, but only within the clinical setting. In view of this, if the new method is not in complete agreement with the established one, is it necessarily wrong? In addition, if the established method does not have total reproducibility, then the agreement between the two methods is bound to be poor, and more so if the new method also does not have robust reproducibility.

Secondly, there is no consistency in the literature on the statistical method used to assess agreement between two methods of clinical measurement. As pointed out by Bland and Altman, the correlation coefficient is not a good indicator of agreement. Indeed, the landmark article by Ganz et al that established the use of the PAC in clinical practice “proved” the accuracy of thermodilution via PAC compared with the conventional dye dilution technique by correlation. Many studies continue to use correlation, making comparisons difficult.

The third reason for the difficulty in evaluating cardiac output monitoring devices is the uncertainty as to what degree of bias and what limits of agreement are acceptable. This is a matter of clinical judgement. How much of a difference would cause problems in clinical interpretation and lead to treatment error? There is, as yet, no clear consensus.

Perhaps our inability to satisfactorily answer the two questions I posed in the first paragraph lies in our failure to answer the hard question of why we are monitoring cardiac output in the first place.

We need to shift our focus. So, to answer the first question, new devices should be evaluated on whether they are able to guide treatment for an improved outcome, so as to avoid the negative aspects that attend the use of the PAC. Evaluating new methods against the PAC is merely a start. The answer to “How close is good enough?” is: “That is the wrong question”. Ultimately, we need to use the appropriate device, to derive the appropriate data, to guide us to apply the appropriate therapy. The question should be, “Does the device yield useful data in my clinical situation?” It is a matter of treating the patient, not the number.

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References


