Comment on the Edwards FloTrac™/Vigileo versus pulmonary artery catheter study: What is really going on with this patient?

INTRODUCTION

The observational study published in this issue of IJCIIS Power et al., compared the reliability and effective usability of FloTrac™/Vigileo (FV) against the traditional pulmonary artery catheter (PAC) in the setting of cardiothoracic surgery. The authors also used echocardiography (transesophageal [TEE]/transthoracic [TTE]) to aid in the comparison of the aforementioned devices, which is described as the first observational study of its kind. TTE/TEE echocardiography combined with PAC is defined as the gold standard by the authors in evaluating cardiac function in postoperative cardiothoracic surgery patients, and its use in this study served as control data.

PULMONARY ARTERY CATHETER

Despite well-known limitations, the PAC has remained the gold standard for decades. It relies on invasive placement, which requires Intensive Care Unit level of care and mechanical expertise to insert and manage. Its invasiveness potentiates the risk of infections and other issues including arrhythmias, pulmonary artery rupture, and death. Though the data can sometimes be misinterpreted, the PAC remains widely used. It also remains cost-effective and can be used in a wide patient population.

FLOTRAC™/VIGILEO

There is no debate regarding the potential benefit of the use of the FV—the debate is whether the technology is suitable for use across a patient population with diverse comorbidities and rapidly changing hemodynamics. The ability to monitor continuous cardiac output (CO) carries many advantages in aiding providers to manage and select appropriate interventions. The FV is favored because it would offset potential risks involved with a PAC. The FV is also significantly less invasive in comparison to the PAC as it uses the radial artery in this particular study, which carries a lower rate of overall complications and requirements for central venous access.

TRANSESOPHAGEAL/TRANSTHORACIC ECHOCARDIOGRAPHY

Both TTE and TEE echocardiography provide valuable information regarding cardiac function, particularly regarding cardiac contractility and valvular function. TTE echocardiography is ideally suited to assess cardiac function as it is easily and noninvasively performed at the bedside and can provide a real-time visualization of cardiac structures. While it does require some technical expertise to interpret, remote reviewing of images facilitates widespread use and many clinicians are quick to learn the basic interpretations.

TEE echocardiography is invasive and requires procedural sedation to perform. However, the TEE echocardiography is routinely used intraoperatively during coronary artery bypass grafting and valvular surgeries, and such data can provide a real-time assessment of physiology and the response to interventions.

DISCUSSION

After reviewing the data in the study, several concerns arise regarding the accuracy of the FV device. The study demonstrates how FV can be compared to the current gold standard, PAC. First, it was used only in a limited segment of the cardiac surgical population. It was not used in atrial fibrillation or in the setting of any significant valvular disorders, particularly in aortic stenosis (AS). The incidence of atrial fibrillation after cardiothoracic surgery is around 31% (n = 1832), and when it occurs, hemodynamic instability is often encountered emphasizing that such technology might be least useful in times of greatest need. Significant AS is not uncommon either estimated as being found in approximately 12.4% of the elderly patient population or 3.4% having severe AS (n = 9723). All these leave the FV as a relative tool in cardiac surgery patients.

In this study, the FV corresponds well with TEE/TTE echocardiography during a “normal” state, outperforming
the PAC. The remainder of the key pathologies (empty, primary systolic failure [PSF], and vasodilation) shows a lower agreement rate between FV and TEE/TTE echocardiography when compared to the PAC and TEE/TTE echocardiography. Although statistical significance is yet to be determined for these findings, this is crucial evidence as these pathologies have potentially life-threatening consequences if interpreted inappropriately. When the cardiac index (CI) was <2.2, the data demonstrate that the FV was outperformed by PAC in both empty (30.8%, n = 13 vs. 57.1%, n = 14, respectively) and PSF states (66%, n = 3 vs. 50%, n = 4, respectively). Statistical significance was not calculated for these phenomena. With all these conflicting data, one cannot help but ask – “what is the real status of this patient?”

SUMMARY

The study, while interesting and important, was not without flaws. The authors claim this is the first study to use TEE/TTE echocardiography as a control when evaluating FV versus PAC in postoperative patients. The kappa concordances calculated favor the FV to the PAC with a normal CI (0.137 vs. 0.057, respectively), though underperformed the PAC during CI <2.2 (0.115 vs. 0.17, respectively). However, the sample size was small (n = 50).

This study demonstrates that there is a need for a continuous CO monitoring tool that is inexpensive, technically simple, widely used, and reliable. This tool should also be accurate across the entire cardiothoracic surgery population despite disease states. More research needs to be done with a larger sample size comparing continuous CO monitoring tools to echocardiogram in an effort to better understand and treat the unique and varying hemodynamics in cardiothoracic surgery patients.

Nevertheless, negative studies such as this one are very important as we rely more and more on bedside technology to manage critically ill patients. Knowing what works, what does not, and in what population and clinical scenarios is critical to good patient care.

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