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EDITORIAL COMMENT

New Approaches to Hemodynamic Measurement

Cool Devices But a Shaky Infrastructure*

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Life is like laying a foundation; you have to build it brick by brick.
Sam Silver (personal communication, June 1960)

Confusion of goals and perfection of means seems, in my opinion, to characterize our age.
Albert Einstein (1)

Arguably late, long after initial heart muscle damage, early cellular, structural, and neurohormonal changes, almost all heart failure can be described, in part, by hemodynamic abnormalities. And knowledge or estimation of a patient's hemodynamic state allows a formulation of a fuller therapeutic plan. Oftentimes the plan incorporating a hemodynamic profile may alter the natural disease progression for a patient (2).

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Given the potential to alter a serious disease state, accurate and instantaneous knowledge of patient's central hemodynamics continues to intrigue all who treat these patients. And so the literature has hosted a debate whether knowledge of an individual's hemodynamics during a small snapshot of time is indeed efficacious (3,4). What may have been on trial, however, is more the evidence base for how to react to a variety of hemodynamic profiles rather than the safety or efficacy of the pulmonary artery catheter technology itself (4).

Recently, the intrigue with knowing a patient's hemodynamic profile has been investigated with either noninvasive (5,6) impedance cardiography technology or by adding such technology to a device commonly implanted in target patients (7). These early studies have enlightened us, at least, to the false premise of presuming that a 1-, 2-, or 3-day snapshot of a patient's hemodynamics using a pulmonary artery catheter at the time of admission to a critical care unit is indeed any form of "gold standard." We nevertheless continue to ask the same questions of any new technology seeking to provide us with a patient's hemodynamics. *First*, what is its ease of use (compared with the pulmonary artery catheter)? *Second*, how well does it correlate with the pulmonary artery catheter during a period of decompensation? *Third*, how safe is it to use (in comparison to the pulmonary artery catheter)? *Fourth*, if it is being used serially or indeed implanted, how much time before a decompensation does it provide warning signals? And *fifth*, and perhaps most importantly, if the goal of monitoring is to reduce morbidity and improve survival, then if the warning signals are heeded and appropriate therapy applied, does it do so?

In this issue of the *Journal*, Verdejo et al. (8) report of still another device seeking to answer many of these questions, which continues the intrigue in knowing a patient's hemodynamics. The authors describe a feasibility trial of the CardioMEMS Heart Failure Sensor (CardioMEMS Inc., Atlanta, Georgia), which is a novel catheter-delivered pressure sensor that is chronically implanted in the pulmonary artery. Alterations in the pressure inside of the artery alters the baseline resonant frequency emitted by the device and then, using an external sensor, the signal is transmitted outside of the body and transduced into a waveform. The external device similarly calibrates for external pressure. The authors describe their experience in 12 patients who had the device implanted and begin to answer several of our questions. Although we know little about how these 12 patients were selected, they are fairly well characterized in a table, and, interestingly, the patients included provide an opportunity to study this device in a fairly broad range of pulmonary artery pressures (mean from 25 to 60 mm Hg).

In terms of ease of use, the authors indicate successful placement in all 12 patients with an average implant time of approximately 70 min but notably as little as 19 min. A single device migration occurred without untoward effects and presumed continued function.

The bulk of the report and figures seek to answer questions of correlation with either echocardiography-derived pulmonary artery pressures or hemodynamics directly measured with a pulmonary artery catheter. These show strikingly good correlation coefficients in the short and medium terms. Unanswered, but sure to be the focus of future clinical trials with this new device, are questions 4 and 5. The authors provide a good discussion of the added value of such a device that can provide real-time evaluation of an accurate pulmonary artery pressure.

So, besides the 2 unanswered questions for this device and others of its genre, there really are 2 additional "overriding" questions from which we should not be dissuaded. We are always excited to welcome new technology to our diagnostic and potentially therapeutic armamentarium; we need, however, to be aware that such devices herald in a new era where serial recording of the patient in a

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"compensated," "decompensated," and every state in between may now be available. We need to sort out how and when to retrieve these signals, how to incorporate them into daily clinical routines and disease management strategies, and how to use information technology to help us decide what signals are the actionable early warning signs of a patient with a forthcoming clinical event (question 4). The devices without a suitable infrastructure will overwhelm the doctors and nurses monitoring these devices, and any potential benefit will be obscured by the burden of the data load. In addition, the sub rosa issue of responsibility and liability for data review and therapeutic decisions is just beginning to surface. Clearly there is a call to action for us to develop the infrastructure needed to incorporate the information era of heart disease management into a new and expanded definition of "integrated disease management programs."

But are we not begging the question? What is needed is more insight and consensus on how to rapidly respond to either the early warning signal of decompensation or that of late, advanced decompensation for that matter. Any metric or meter is simply diagnostic. It puts before the clinician information that must be integrated and acted upon. Each day I am amazed at how different are the responses to the same clinical scenario. Guidelines notwithstanding, clinical variability abounds in heart failure care. The variability, coupled with a mystical presumption of therapeutic effectiveness of simply having hemodynamic measurements, remain the very stumbling blocks of our foundation upon which we need to design the building of improved outcomes for our patients. So I, as do we all, welcome the engineering and technological advances that are leading us to new and better ways to know a patient's hemodynamic profile, perhaps even continuously, but we should not forget to create, in parallel, the knowledge base, which will allow us to capitalize on these new advances.

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