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EDITORIAL

When should we adopt continuous noninvasive hemodynamic monitoring technologies into clinical routine?

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The introduction of new technologies for noninvasive continuous hemodynamic monitoring requires the conduction of well-planned clinical studies in order to assess the technology's measurement performance and to evaluate the potential benefit for the patient. But what is the right way to go with regard to clinical validation and evaluation studies from the technology's first introduction to its medically useful application on a routine basis? From the article by Benes et al. [1] a general recommendation for a reasonable approach in order to answer this question can be derived.

The existence of methodologically and statistically solid validation studies must be the prerequisite for any further scientific investigation of a potential clinical benefit of noninvasive continuous hemodynamic monitoring technologies. In order to assess a new technology's accuracy and precision and thus its measurement performance in validation studies, we need the comparison with invasive arterial catheter-derived measurements as the clinical criterion standard method. However, invasive hemodynamic monitoring is usually reserved for critically ill and high-risk surgical patients. Therefore, the first step on the path towards establishing a new noninvasive technology must be the performance of validation studies in these patient groups equipped with invasive hemodynamic monitoring that can be used as a reference method [2, 3]. We should then carefully and critically check a new noninvasive technology's validation data in order to avoid misinterpretation of the technology's measurement performance. We must avoid performing premature outcome-oriented studies using devices and algorithms that have not been meticulously validated or that are simply not precise enough. Sometimes we might have to take a step back after the first validation data and try to improve the technology's algorithms and technical shortcomings before proceeding to the next level of studies. Only when meticulously performed validation studies are available it will make sense—from a scientific and clinical point of view—to proceed to the second step.

This next step is to precisely define the right target patient groups and clinical scenarios for the sensible application of the noninvasive continuous hemodynamic monitoring technology. At present, a recommendation to use a noninvasive continuous blood pressure measurement technology instead of an arterial catheter in critically ill patients treated in the intensive care unit or in high-risk surgical patients would not be appropriate. Instead, we should rather focus on patients who do not receive continuous hemodynamic monitoring but intermittent blood pressure measurements using oscillometry. Benes et al. [1] rightly decided to include low and intermediate-risk surgical patients during thyroid surgery in beach chair position. Thereby they offer us an excellent example for the possible use of noninvasive continuous blood pressure monitoring as a reasonable alternative to intermittent oscillometric blood pressure measurements in the perioperative setting. Other scenarios in which continuous noninvasive blood pressure measurement might contribute to the patient's safety have been recently proposed [4, 5]. After having precisely defined patient groups and clinical scenarios for the new technology's application, the third important step is conducting studies that are related to patient safety and outcome. Such studies might assess hospital mortality, hospital length of stay, or complication

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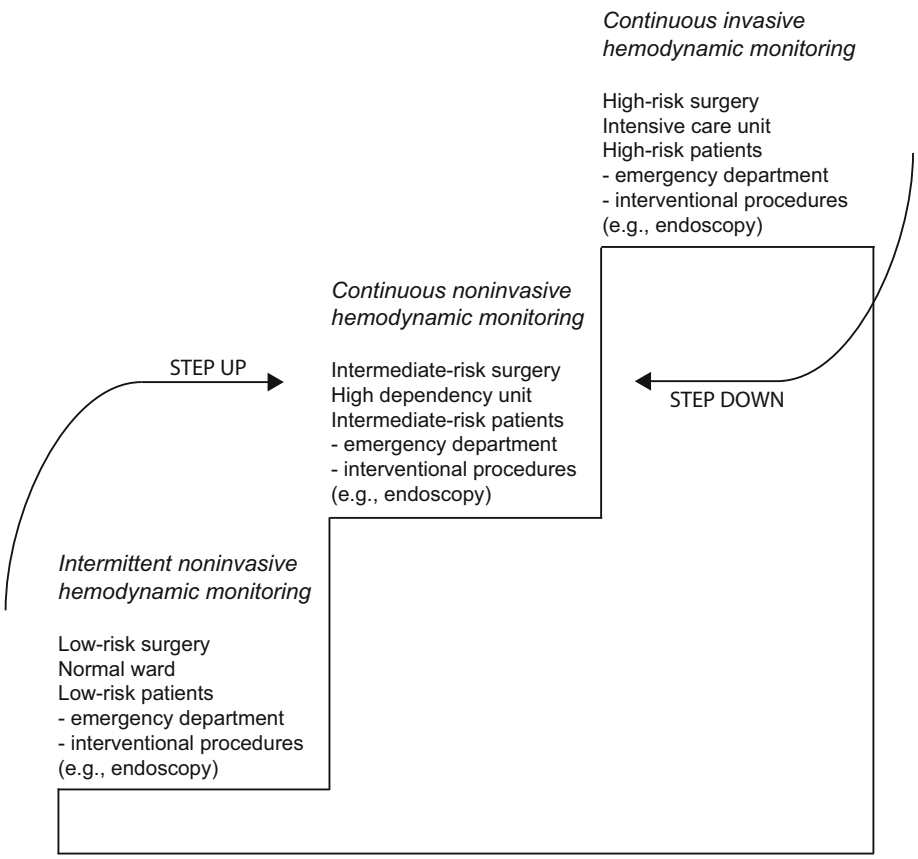

Fig. 1 Clinical settings for the application of continuous noninvasive hemodynamic monitoring technologies

rates. A well-conducted randomized controlled trial assessing the impact of goal-directed therapy based on parameters assessed with a new noninvasive monitoring technology on patient outcome is the final important step from the introduction of an innovative technology to its application in a clinical setting outside of studies.

However, despite promising data, innovative noninvasive hemodynamic monitoring technologies are often discussed controversially. Interestingly, when discussing the reasons for a lack of acceptance of the new technologies, one must be aware of a significant discrepancy between objective data from well-conducted and statistically sound clinical studies and what clinicians and medical societies have adopted as the clinical standard. This discrepancy can be illustrated through the example of the oscillometric method for blood pressure measurement. Oscillometry is broadly used with great confidence in the methodology despite a lack of strong evidence for accuracy and precision of the method. In fact, multiple non-standardized manufacturer-dependent algorithms for oscillometric blood pressure measurements exist and validation data are often missing or not readily available [6]. Several limitations of oscillometry have been shown. In a huge database of non-cardiac surgery patients, Wax and colleagues demonstrated a low precision of oscillometry compared with invasive blood pressure determination with an overestimation of low and an underestimation of high blood pressure values [7]. Lehman and colleagues recently used a large intensive care unit database to compare invasively obtained and oscillometrically derived blood pressure and demonstrated clinically significant discrepancies between the two methods [8]. Further, oscillometric blood pressure is less reliable in patients with atrial fibrillation [9] and in obese critically ill patients [10]. Based on these findings it is not presumptuous to claim that oscillometry is not clinically acceptable compared with the invasive arterial catheter. However, it seems that the user's confidence in the technology is far more important for its broad application and acceptance in the clinical routine than the technology's actual objective measurement performance itself.

In conclusion, in order to ensure the patients' maximum benefit, our current goal should not be the general replacement of invasive hemodynamic monitoring by noninvasive technologies. Instead, we should first of all define clinical settings (Fig. 1) in which new noninvasive hemodynamic monitoring technologies can improve patient safety by either providing continuous beat-to-beat hemodynamic data instead of intermittent measurements or by avoiding the risks related to the insertion and presence of an arterial catheter.

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