Dr. James P. Rathmell: Hello. I'm Jim Rathmell, Professor of Anesthesia at Harvard Medical School and Chair of the Department of Anesthesiology, Perioperative and Pain Medicine at Brigham and Women's Hospital. I'm one of the Executive Editors for Anesthesiology and you're listening to an Anesthesiology podcast that we've designed for physicians and scientists interested in the research that appears in the journal.

Today we're going to talk with the lead author of an original research article and an accompanying editorial view that appear in the March 2020 issue. With us today is Dr. Martine Breteler. Dr. Breteler works as a Clinical Investigator in the Department of Anesthesiology at the University Medical Center in Utrecht in Utrecht, The Netherlands.

Dr. Breteler is the first author on that article that appears in the March 2020 issue of the journal and it's titled “Vital Signs Monitoring with Wearable Sensors in High-risk Surgical Patients.” Dr. Breteler, thank you for joining us.

Dr. Martine J. M. Breteler: Thank you for the invitation. It is now my pleasure to participate in this talk now.

Dr. James P. Rathmell: Also with us today is Dr. Bernd Saugel. Dr. Saugel is Professor in the Department of Anesthesiology within the Center of Anesthesiology and Intensive Care Medicine of the University Medical Center Hamburg-Eppendorf.

Dr. Saugel wrote an editorial view that accompanies Dr. Breteler's research article in the March 2020 issue of the journal and it's titled “Automated Continuous Noninvasive Ward Monitoring: Validation of Measurement Systems is the Real Challenge.” Dr. Saugel, thank you for joining us.

Dr. Bernd Saugel: Hello, everybody. Thank you very much. I am very happy to have the opportunity to discuss this highly interesting paper on innovative ward monitoring systems.

Dr. James P. Rathmell: Dr. Breteler, congratulations on publishing this innovative look at these emerging new technologies. I want you to help me set the stage for listeners. Now, changes in vital signs are an important indicator of physiologic decline; we know that and these changes provide opportunities for us to recognize this deterioration early and to intervene.

But when patients are on hospital wards, vital signs are usually measured just intermittently. And in between the spot checks, these early signs of deterioration could be missed. So, we have several of these wearable and wireless sensors that have been developed that may be able to capture this patient deterioration earlier.

Can you start by describing some of the wearable sensors that you’ve studied and what do they look like and how do they actually work?

Dr. Martine J. M. Breteler: I can. So, in the past years, several wearable and wireless sensors intended for continuous vital signs monitoring became available. These sensors allow the patient to move freely without being attached to a wired patient monitor.

So, in this study we used four different sensors: the first is a patch sensor; it’s called SensiumVitals and it’s placed on the patient's chest by means of two conventional ECG electrodes and it measures heart rate, respiratory rate and accelerated temperature every two minutes for up to five days.

And these measurements are wirelessly transmitted via radio protocol to so-called hotspots in the hospital and then sent to a secured central monitoring server within the hospital.

Another patch we studied, a second patch sensor, is called the HealthPatch and this is also an adhesive biosensor placed on the patient’s chest and it measures a number of variables such as heart rate, respiratory rate, single-lead ECG, skin temperature, body posture, and step count.

And these vital signs are even updated every four seconds and it can measure up to four days and the sensor then transmits data via Bluetooth to a relay device after which it’s being sent to a secure cloud server.

Another third sensor we used in our study was the EarlySense system and this is a contactless (inaudible) electric sensor placed under the patient’s mattress and it connects to a bedside monitor that displays heart rate, respiratory rate and body motion once every minute as long as the patient remains in bed.

And the fourth sensor we used is the Masimo Radius-7 and that is a patient wearing a monitor connected to the pulse oximeter probe attached to the finger to measure a pulse rate and oxygen saturation and a novel acoustic piece of sensor applied in the neck to measure respiration rate. And this device was worn on the upper arm and wirelessly connects to the bedside monitor to show the vital signs.

Dr. James P. Rathmell: That’s perfect. So, the people listening can get a good sense of these monitors. They’re really simple. I mean, stick-on monitors or a receiver or a detector device that fits in the bed or in the form of a traditional pulse oximeter with a little bit of additional detector device. So, pretty easy to use.

You set out to test several of these devices and how reliably they can measure heart rate and respiratory rate. So, what was the hypothesis for this study?

Dr. Martine J. M. Breteler: Well, our hypothesis was that these wireless sensors can monitor heart rate and respiratory rate reliably when compared to traditional “wired” reference standards. But to be honest, we did not know how their performance differed from each other and how well they performed against reference solutions.

And just to give you an idea, when we thought of this interesting topic a couple of years ago, we realized that the majority of these sensors were not validated in relevant clinical environments but most of the time only in lab environments.

So, even when a (inaudible) is available, if they use it as a medical device, it does not mean that it can actually detect physiological decline in patients.

Dr. James P. Rathmell: Yes, that’s really important. So, reliability. You set out to say, “Does this sensor or this group of sensors actually detect what we want it to detect?” So, you had to measure it against a gold standard—you’re going to tell us a little bit about that in a minute—and you wanted to test that reliability against a gold standard in a true clinical setting.

So, tell us how you conducted the study. What kinds of patients did you enroll and how did you actually test the reliability of the devices?

Dr. Martine J. M. Breteler: Yes, by doing this we performed an observational method, a comparison study in which high-risk surgical patients were continuously and simultaneously monitored with the four new wireless sensors I just mentioned. And we compared it with an intensive care standard beside monitoring system which served as a reference monitor.

And we monitored these patients during the initial days of recovery at a surgical step-down unit until they were transferred to either the traumatology ward or the surgical oncology ward. And we considered these patients because these are more prone to deteriorate when compared to patients on the general ward and as such, we could validate heart rate and respiratory rate not only in a normal physiological range but also in patients that show physiological decline.

While we tested that, we tested the reliability by—well, our primary outcome was the agreement of heart rate and respiratory rate measurements between each of the wireless sensors and the reference method. As we tested this while using Bland-Altman analysis for repeated measurements and we determined the mean of the differences which is called the bias and the limits of agreement.

But we also did use secondary endpoints where we more looked into the clinical relevance of the differences found and therefore we used Error Grid...
analysis to find information about the consequences of incorrect treatment positions when using measurements of each of the wireless sensors.

And besides this, we also wanted to know whether the wireless sensors are able to track changes in vital signs over time because in the end we’re not only interested in a single absolute measurement, but we want to know whether a patient’s condition is improving or deteriorating.

And for this analysis we used four-quadrant plots and concordance rate analysis to identify where the measurements of a wireless sensor change in the same direction as compared to the reference.

Dr. James P. Rathmell: So, you primarily were looking at reliability, but you also looked at how this data might be used clinically and I want you to talk a little bit more about it, then. You did end up enrolling 25 high-risk surgical patients and you collected more than 700 hours of data from these four devices for analysis comparing it against the Bedside Reference Standard. What did you learn?

Dr. Martine J. M. Breteler: Well, we learned many, many things. First of all, these wireless sensors tested, we are able to accurately measure heart rate. The respiration rate was more difficult to measure, but the accuracies of Masimo Rad-7, the EarlySense System and SensiumVitals were within our predefined range. But the HealthPatch sensor tended to overestimate respiration.

But we also learned that our reference standard used cannot be considered a true gold standard for respiration rates. So, we used our current ICU monitoring system, and that’s our standard monitor throughout the hospital in all high-care facilities. But as soon as a patient moves or talks, wide variation in observed respiration rate can be seen at the bedside ICU monitor of these patients.

So, we need to accept that a part of the margin of error is possibly related to deficiencies in the reference standards rather than the wireless sensor. I even do believe that a wireless sensor might outperform traditional wired reference standards. And, lastly, we also realized that guideline for acceptable limits of agreement with continuous vital signs monitoring does not yet exist.

For example, we considered respiration rate acceptable for our clinical process if it stays within three breaths per minute of the reference standard. But in clinical practice it’s not so relevant whether the respiration rate of base units either 32 or 35; it’s high anyway, but for low respiration rates, for example, it is critically important to know when a patient’s respiration is either eight or five breaths per minute. So, it might be clinically desirable to redefine acceptable accuracy limits depending on the value of the vital sign measures.

Dr. James P. Rathmell: Some pretty interesting observations there. All of the wearables were highly accurate for detecting heart rate and almost all of them were accurate for detecting respiratory rate, but a bunch of questions came up when comparing it to a reference standard: does the reference standard actually detect the true respiratory rate? So, what did you conclude from the study?

Dr. Martine J. M. Breteler: Yes, that is indeed correct. And although respiration rate is more difficult to measure, these wearables were accurate enough to identify at normal patterns, at normal trends patterns for respiration rate.

And we need to realize that these devices are not designed to substitute continuous ICU monitoring grade systems, but we can conclude that wearable sensors for vital signs monitoring could be valuable tools to reduce failure-to-rescue events in patients outside high-care facilities.

Dr. James P. Rathmell: So, they may be coming to a bedside near us soon. Dr. Saugel, I want to turn to your editorial view. For the listeners, again, the editorial is entitled “Automated Continuous Noninvasive Ward Monitoring: Validation of Measurement Systems is the Real Challenge.”

Dr. Bernd Saugel: Well, you are right. When patients after surgery reach the post-anesthesia care unit, we assume and families assume that they have survived the most dangerous part of the perioperative experience. This assumption, for sure, is wrong. The major complications occur in the initial days and weeks after surgery and that is when most of the patients are treated on a normal ward.

We know that alterations in vital signs are early signs of complications and, therefore, identifying hypotension, tachycardia, hypoxemia or high respiratory rate using ward monitoring systems is an intriguing concept of avoiding complications.

Ward monitoring systems for blood pressure, heart rates, oxygen saturation, respiratory rates or even body position, activity and body location are already available. However, before we design clinical trials investigating if these systems improve patient outcomes and before using these technologies in clinical practice, we need to overcome a number of crucial limitations and problems.

And in my opinion—and that is why this paper is so very important—one major challenge is that we need to rigorously test the measurement performance of ward monitoring systems and validate them in different clinical settings before we proceed to clinical trials or to using it in clinical practice.

Dr. James P. Rathmell: So, the devices are available but they really still need to be rigorously tested. How much new information did Dr. Breteler’s study add to our understanding of how and when we might be able to use these wearable monitoring devices?

Dr. Bernd Saugel: Martine and her team used very solid statistical tests to compare noninvasive standards for ward monitoring with the reference method; in this case, intensive care unit monitoring.

As she already mentioned, the primary outcome was the absolute agreement of heart rate and respiratory measurements and they used Bland-Altman analysis and that showed that for both of those vital signs, heart rate and respiratory rate, the mean of the differences was low. The mean of the differences reflect the trueness of the measurements that is often also called the accuracy. So, the trueness was good.

However, the relatively wide limit of agreement in Bland-Altman analysis indicates that the precision of agreement of the test method in comparison to the reference method still need to be improved. As also already mentioned, the secondary endpoint—and that is highly clinically relevant—was that they looked for the clinical relevance of measurement differences between the test and the reference method and they used Error Grid analysis to assess this endpoint.

And this showed that in the vast majority of the patients, the measurements for the test method would have triggered adequate treatment decisions. And in addition, the study shows that ward monitoring systems tested in the study may be useful to follow changes in vital signs over time. That means that the trending ability of the devices was pretty good.

So, in summary, the analysis of continuous ward monitoring devices shows promising results, but it also emphasizes that ward monitoring can only improve patient outcome when the measurements are accurate and precise and this study shows that there is still room for improvement regarding the measurement performance.

Dr. James P. Rathmell: So, the study is a good start but we still need a lot more work on validating the devices and the precision isn’t what we would hope it would be.
So, once they are validated, once we have valid precise measurements, what work needs to be done before we can actually use these devices in any practical way in everyday patient care?

**Dr. Bernd Saugel:** Before we can recommend using ward monitoring in clinical practice, we need to perform large-scale, clinical trials investigating whether continuous ward monitoring and, of course, even more important, interventions triggered by ward monitoring can eventually improve quality of care in patient outcome.

In addition, there are technical challenges that need to be addressed and I will just mention a few of those. Of course, ward monitoring sensors need to be small, wireless, easy to use and able to communicate with mobile devices or patient monitors.

Sensors should be able to record and process different vital signs and not just one to minimize the number of different sensors that need to be attached to the patients.

In addition, artifacts need to be filtered to avoid alarm fatigue and the systems need to be integrated in electronic patient records. Then, data need to be processed and analyzed in real time to identify patients at risk and to be able to trigger an intervention by medical caregivers, for example, as a rapid response team.

Other challenges with continuous ward monitoring will be how to handle those very dense data streams, if you monitor numerous patients at one time, and there will be legal issues regarding data protection and privacy rights.

**Dr. James P. Rathmell:** So, there’s a lot that still has to come and I think it’s important you’ve emphasized that the real practical workflows, even if we have accurate, precise transmission of data, when do we react and how do we react? The infrastructure to actually react to these alarms has got to be in place. So, when do you predict that we’ll see these devices in common use after surgery?

**Dr. Bernd Saugel:** This is a difficult question and depends on the vital sign we want to monitor. There are reliable technologies for continuous ward monitoring of heart rate and respiratory rate and the study by Martine and colleagues show that very nicely.

In contrast, blood pressure ward monitoring is very challenging. Blood pressure is a complex hemodynamic signal and reliable continuous noninvasive blood pressure monitoring on the normal ward is technically challenging and I’m not aware of a system that is available at the moment to provide reliable, continuous blood pressure monitoring in the setting of a normal ward.

That means there are already systems that continuously monitor physiologic variables like heart rate and respiratory rate and I’m pretty optimistic new biosensor material and digital developments will allow buildings better measurement systems and systems for noninvasive continuous blood pressure monitoring in the near future.

So, I expect—that is my personal point of view—that continuous real-time assessment of a patient’s vital signs will become clinically routine in a couple of years from now and then as a next step we may then focus on how to expand ward monitoring to even home monitoring in the periods after hospital discharge.

**Dr. Martine J. M. Breteler:** Yes. Well, we have a few projects we are currently working on and I’d also totally agree to the points which Dr. Saugel just mentioned because we just started a clinical trial together with Amsterdam University Medical Center where we use the sensing system, so one of the wearable patches evaluated in this study, to test the hypothesis whether continuous monitoring of vital signs in surgical patients at the ward will actually improve patient outcome.

And we are doing this with a so-called stepped wedge design where we will cross over four participating wards to the intervention phase during which continuous monitoring is implemented and this will hopefully get some interesting results in the upcoming years.

We are also participating in an EU-funded project called Nightingale and this is a collaboration of five European academic all-stars where we are currently working with two MedTech companies in Europe who are building a wireless patient-monitoring solution that use clinical decision support systems to identify which patients are at risk of deterioration, both on the wards and at home after hospital discharge.

And not only the ability to continuously measure blood pressure noninvasively is an (inaudible), for example—and I have to mention this is quite difficult, but I’m sure we will get there in a couple of years—but also the value of adding soft signs such as nurse’s worry or using lab values (sounds like: app) in predicting which patient needs attention (inaudible).

And I personally—I really do believe that it’s not only vital signs monitoring with wireless sensors that enables us to earlier identify patient deterioration, it is the added value of using this together with sophisticated alarm strategies in combination with nurse’s input of their clinical judgment and other soft signs derived from patients themselves.

**Dr. James P. Rathmell:** So, that’s pretty neat. So, that adds to the clinical judgment of the person who’s at the bedside. They’re worried, it gives you additional data on which to base a decision. Fantastic.

Well, I hope today’s discussion is going to lead many of you listening to find new article and editorial view that appear in the March 2020 issue of Anesthesiology. You can learn more about wearable monitoring devices and their use after surgery.

Dr. Jon Wanderer from Vanderbilt and I also create an infographic that appears in the same issue and it’s titled “Continuous Postoperative Monitoring: Validation of the Next Frontier.” We aim to place the major findings of the study into perspective.

Drs. Breteler and Saugel, thank you very much for joining me today and for your terrific explanations.

**Dr. Martine J. M. Breteler:** It was my pleasure. Thank you.

**Dr. Bernd Saugel:** Thank you very much. It was a pleasure discussing this highly interesting research with you.

**Host:** You’ve been listening to the Anesthesiology Journal podcast, the official peer-reviewed journal of the American Society of Anesthesiologists. Check anesthesiology.org for an archive of this podcast and other related content.