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Understanding the 4-Strata Approach to Risk Assessment (RA) for Patient Monitoring and Management

Announcer:

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Dr. McLaughlin:

Hello, I'm Val McLaughlin from the University of Michigan, and welcome to this didactic session on PH risk stratification in 2023, Understanding the 4-Strata Approach to Risk Assessment for Patient Monitoring and Management.

And I'm really excited about this methodology. We've talked in the past about the 3-strata approach. And while it's very good, while we've learned a lot about risk assessments over the years, the limitation with the 3-strata approach is that intermediate group is a very broad group of patients, about 70% of patients fall into the intermediate-risk group. And there is a wide variety in that group. And as I see those patients over the years, you know, there's some that I'm much more worried about and that I want to treat more aggressively, and there's some that I'm less worried about. And so there is recent data on now using a 4-strata approach for risk assessment in this patient population.

So there were a couple of papers that came out over the past year or so from large registries in Europe, initially, the COMPERA registry, and then this was validated in the French registry, that looked at cut-points to try and determine the difference between patients at the lower end of intermediate risk, and patients at the higher end of intermediate risk. And the methodology is very similar to the 3-strata by using a point system assigned for patients in the various risk categories. So it again uses the noninvasive approach. So just functional class, 6-minute hall walk, and biomarkers. And this is something that we do in clinic every time we see patients. So we can do this 4-strata risk assessment, really at every single clinic visit. And we know the low-risk criteria are being functional class 1 or 2, having a hall walk over 440, and then some biomarker cut-offs, a BNP less than 50, or NT-pro less than 300. And you can see the cut-offs here for intermediate-risk and high-risk as well.

And so what we do is assign a point system based on the functional class, the 6-minute hall walk, and the biomarkers, and then we divide by that number of 3 that are measured and come up with a score that's then rounded to the nearest integer. And intermediate-risk group is now broken out into intermediate-low and intermediate-high.

And the data from the COMPERA registry really nicely shows the difference in outcomes in patients at intermediate-low and intermediate-high, and it's more sensitive to changes. So here you see the outcomes based on their intermediate - their risk status at baseline and then with follow-up, with green being low, the light yellow being intermediate-low, the orange being intermediate-high, and the red being high. And you can see that this methodology is predictive at baseline. And then you can even see the curves separate at follow-up. And you can see there's a clear difference in outcomes in patients who are at intermediate-low and intermediate-high risk. And I think this is clinically relevant, and really impacts how we might manage patients.

Now whenever you see something done in one registry, you want to have it validated and see if it applies to another patient population. And these papers were actually published back-to-back in the *ERJ*. The methodology that was determined in the COMPERA registry

was then validated in the French registry, they used the exact same cut-offs and looked at outcomes in patients based on those 4 risk strata.

And here in these outcome curves to the right, you can see on top the 3-risk model at baseline and follow-up, and then on bottom, the outcomes according to the 4-strata methodology. And once again, you see these 4 distinct curves that even separate further based on response at the first follow-up visit. And you can see those intermediate-risk groups are different. Intermediate-low is different than intermediate-high. And intermediate-high, even though it's still intermediate is very close to high. And I think this is really important as we decide how to treat patients.

Another important point is that this methodology is now more sensitive to change using the 3-strata method on the left, you see there are a handful of patients who move from high risk to intermediate and, you know, not so many that move from intermediate to low, but it's really almost all intermediate. Whereas on the right, with the 4-strata methodology, you see more movement, more sensitivity to response of therapy.

Now, we couldn't talk about risk assessment unless we also mentioned the REVEAL calculator as well. And there have been some modifications to the REVEAL risk calculator, the 2.0 has now been advanced to what we call 2.0 Lite, where it essentially takes away some of the non-modifiable variables such as disease, etiology, age, gender, and it relies just on some modifiable variables, including functional class, hall walk, biomarkers, vital signs, and renal function, and it is also an important prognostic indicator.

So to sum up, we now have more sensitive tools to assess risks. And the ERS/ESC guidelines recommend that that first follow-up risk assessment now use the 4-strata method. And I think clinically, it's really important to divide that intermediate risk group into intermediate-low and intermediate-high. And I enjoy using this 4-strata methodology in my clinic as I follow up my patients.

So thank you so much for joining me for this discussion on the 4-strata method for risk assessment.

Announcer:

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