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Cutting-Edge Trials: TAVR for Small Aortic Annuli

Announcer:
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Dr. Ukaigwe:
This is CME on ReachMD and I'm Dr. Anene Ukaigwe. I'm going to review the latest information on transcatheter aortic valve replacement platforms in patients with a small aortic annulus. Let's dive in.

Basically, small aortic valve annulus accounts sometimes up to 40% of all aortic valve replacements, with the predominance of women, non-Caucasians, and patients undergoing valve-in-valve, and this is defined as an annulus area that is less than 430 mm square on 3D CT, or annulus diameter that is 23mm or less on ECHO or direct intraoperative measurement.

Now, a normal mean aortic valve diameter is about 21 in females to 23 in males, plus or minus 2 millimeters, and that's perfectly fine for the hemodynamics of most people, except extremes of body surface area. Now, the problem arises when a valve replacement is required because the label size matches this mean aortic diameter, however, the inner diameter of all prosthesis is smaller than this labelled size, or outer diameter, which then leads to a smaller effective orifice area and increases the risk of patient-prosthesis mismatch, which means that the valve is no longer sufficient from the hemodynamic perspective to sustain the cardiac output for the body surface area, which then translates to bioprosthesis dysfunction, persistent adverse LV remodeling, impaired survival, and impaired prosthesis durability.

When it comes to transcatheter aortic valve replacements, all that we really have is the valve design and the two predominant, longest available, transcatheter aortic valve replacement prostheses are the balloon-expandable intra-annular prosthesis and the self-expanding supra-annular prosthesis.

Now, the balloon expandable prosthesis, it's a valve – a bovine leaflets that are sewn within a tubular cage. And where it's sewn is the commissures that reduces the diameter of the geometric orifice area, which then translates to less effective orifice area that would then be smaller than the label size of, or the diameter of the prosthesis.

Now, with the self-expanding supra-annular prosthesis, the commissures where the valve leaflets are sewn together are causing a supra-annular position, and this valve is wine glass-shaped, and therefore this is sewn right around where the valve flares out and there's a small millimeter gain in the perimeter of this geometric orifice area compared to what the diameter of the prosthesis is, which will be about where the stem of the glass will be. And this also then translates to small, but effective increases in the effective orifice area.

This OPERA-TAVI study was a propensity matched registry study that looked at patients that had a small annulus defined by 3D CT undergoing TAVR with Evolut self-expanding or Sapien balloon-expandable valves. And with respect to hemodynamics, the self-expanding was superior. There was no difference in paravalvular regurgitation, but there was an increase in stroke in patients

undergoing self-expanding prosthesis, but again this was a registry study.

Now, all of these then leads us to try to figure out these differences that we are seeing in the design in the registry study, what does that translate to in a randomized controlled trial? And that led to the design of the SMART study that essentially enrolled people with annulus that is less than 430, and who had anatomic suitability for either transcatheter prosthesis and randomized them one-to-one to either balloon-expandable or self-expanding prosthesis. And when they did that, they found that, one, in terms of baseline characteristics the groups are similar, but there were almost 90% of patients were female, which again underlies the fact that small annuli tend to happen more commonly in female patients, which is anatomic and physiologic, from what we know.

In addition, they found that with the annular sizes were similar between both groups, while the procedure was slightly longer in the self-expanding, repositionable prosthesis deployment. And there was a slightly increased risk of permanent pacemaker requirements between the self-expanding prosthesis.

With respect to hemodynamics, the self-expanding prostheses were superior to the balloon-expanded prosthesis in terms of mean gradient at 12 months, effective orifice area at 12 months, moderate to severe patient-prosthesis mismatch at 30 days, and there was a lower chance of bioprosthetic valve dysfunction or adverse hemodynamics at 12 months in the self-expanding, compared to the balloon-expanding prosthesis.

Now it wasn't just that. It found that there was a statistically significant difference in improvement in the quality of life as measured by the improvement in the KCCQ score favoring the self-expanding prosthesis, which suggests that the improved hemodynamics we saw translates to patients feeling better.

However, there was no difference with respect to mortality, disabling stroke or heart failure hospitalization when you compared both prostheses, and that is not surprising because it's still a little too early to tell these differences. And there's a pre-specified follow-up out to 5 years that will help elucidate this.

So, in summary, the SMART trial is the most rigorous trial to randomize patients with the two most widely used TAVR devices. It enrolled mostly women and there was non-inferior clinical outcomes at one year, superior valve performance at one year with respect to hemodynamics and bioprosthetic valve degeneration, and improvements in quality of life that favored the self-expanding prostheses.

Well, that was brief, but I'm glad I had the opportunity to share this with you today. And unfortunately, our time is up. Thanks for listening.

Announcer:
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