STEVE OMMEN: Hello, I'm Steve Ommen. I'm the Chair of Clinical Practice of Cardiovascular Diseases at Mayo Clinic, and today I'm joined by my colleague, Dr. Raul Espinosa, who is one of our pacemaker specialists. Thank you for joining us.

Raul, there's been a lot of attention recently focused on the tricuspid valve and its interaction with pacemakers and defibrillator leads. And today I want to talk about the special case of tricuspid valve prostheses. From your standpoint, what do we need to think of in terms of clinical implications for pacemaker and defibrillator leads in patients with tricuspid valve prostheses?

RAUL ESPINOSA: Yeah-- thank you, Steve. It's a pleasure to be here. As you've correctly said, it's recently been recognized that device leads, be they pacemaker or defibrillator leads, have the potential to interfere with the function of native tricuspid valves, giving severe tricuspid regurgitation and the need for valve replacement over time. And so it's natural to wonder whether tricuspid bioprostheses are vulnerable to the same problem.

Of course, with mechanical tricuspid prostheses, we can't replace a transvenous device lead across the prosthesis. So the issue would not apply to that group of patients. But in patients with tricuspid bioprostheses, the lead can be crossed with a device lead. And so the question is certainly quite germane as to whether we damage the lead with transvenous devices and increase the risk of the lead-- of the prosthesis rather, requiring replacement prematurely.

And so we reviewed, retrospectively, a series of 58 patients-- collected from 1997 to 2010-- who had a tricuspid prosthesis and compared that group of patients who received a transvenous device lead with a controlled group of patients-- about 265, who received a tricuspid bioprosthesis during the same time frame and did not require a device-- and compared the outcome over time in terms of the function of the prosthesis, looking for greater than moderate tricuspid regurgitation in the two groups.

STEVE OMMEN: And what did you find from your study? What were the main findings?

RAUL ESPINOSA: So we found that our initial hypothesis that device leads would impair the function of the tricuspid bioprostheses to not be correct. Recognizing the limitations of a retrospective review, we found that in the group of patients who had a tricuspid bioprosthesis, only a small percentage of patients who required a pacemaker or defibrillator lead went on to develop greater than moderate tricuspid regurgitation over time, about 9%. By comparison, in the control group of patients who had a tricuspid bioprosthesis but did not require a pacemaker or defibrillator lead over an average followup of two years, only about 5% of patients required or were noted to develop significant tricuspid regurgitation-- so 9% in the group that received a device lead and 5% in the group that did not-- a difference that was not statistically significantly different.

STEVE OMMEN: You mentioned the limitations of a retrospective review. Were there other limitations that you've identified in your study design?

RAUL ESPINOSA: Yeah, I think that the results of the study are quite compelling. And within the context of a retrospective review, a quite reassuring study that transvenous device leads can be placed with safety across the prosthesis. But the limitations of the study beyond its retrospective nature were a few.

Firstly, the study had a followup of about two years. So although I think we can feel quite reassured that within the first two years of the life of the prosthesis that the presence of a lead across the prosthesis does not seem to jeopardize the integrity of its function, but we don't have good data beyond two years. And so we would hope that that milieu would persist over time, but we simply don't know for sure.

Also, given that the study group of 58 patients was a relatively small number of patients and event rates were low-- 9% in the study group, 5% in the control group-- it's possible that had we been able to acquire a larger study group and followed it over a longer time frame that perhaps a statistically significant difference would have emerged. But I still think, for clinical practice, to see that over two years of followup-- with a fairly robust group size, both study group and control-- that there was no statistically significant difference, and I think that's helpful for clinical practice.

STEVE OMMEN: Is there any difference between defibrillator leads and pacemaker leads in terms of their interaction with the tricuspid valve prostheses?

RAUL ESPINOSA: Yeah, that's a great question. Defibrillator leads tend to be a little larger. So although we don't know the mechanism of lead-induced valve dysfunction, particularly in the setting of a bioprosthesis, it stands to reason that a defibrillator lead, by virtue of its larger size, might increase the risk for damage to a bioprosthesis. And, unfortunately, in our study, only about 10% of the patients had a defibrillator as opposed to a pacemaker. So I think we can feel pretty good about the safety of placing pacemaker leads across a bioprosthesis, a little more uncertainty with defibrillator leads.

STEVE OMMEN: Raul, thank you for those important insights on your study looking at the safety of device leads and tricuspid valve bioprostheses. And I thank the audience for being with us today and please check back with us for future versions of this series. Thanks so much for being here.

RAUL ESPINOSA: You're welcome.