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The pathway toward the success of a new transcatheter aortic valve replacement device: A surgeon's adventure

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1 **The Pathway Towards the Success of a New TAVR Device –**
2 **A Surgeons' Adventure**

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1 **Central Message**

2 A novel TAVR device needs to take the next steps towards success: enhanced
3 image guidance and demonstration of reproducibility.

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10 **List of abbreviations**

11 TAVR: Transcatheter Aortic Valve Replacement.

12 3D: Three Dimensional

13 TEE: Transesophageal Echocardiography

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Text

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29 Implanted for the first time in a human patient in 2014, the J-Valve transcatheter
30 aortic valve replacement (TAVR) concept has scored significant advancements. In
31 perspective, it can be an attractive option for TAVR in aortic regurgitation, with a
32 good deal of potential for success. The current paper [1] represents the first report of
33 early and follow-up outcomes in a significant number of patients treated with this
34 device. Unquestionably, this experience remains limited in terms of number of
35 implants and amount of patient-years of follow-up. Yet, some prominent aspects
36 deserve to be underlined.

37 First, this technology has been developed through the contribution of cardiac
38 surgeons, who also currently are its only users, testifying once again the vitality and
39 the propensity towards evolution of our discipline. Second, the separation of locators
40 and valve – and their consequent deployment in differed times – represents a typical
41 feature and, potentially, an effective mean to improve immediate results (perivalvular
42 leakage, anatomically coherent positioning) especially in aortic regurgitation cases.
43 Nonetheless, the rate of perivalvular leakage reported herein remains important and,
44 not surprisingly, greater in aortic stenosis cases. It appears that the effectiveness of
45 this TAVR concept relies on optimal landing of the locators at the nadir of each native
46 aortic cusp: irregular calcifications in aortic stenosis reasonably represent an
47 anatomical obstacle in several cases. Missed positioning of the locators – as
48 acknowledged by the Authors – is at the root of many instances of paravalvular
49 leakage in both regurgitation and stenosis cases. To such respect, bicuspid valve
50 anatomy can be considered as a foe for the success of this TAVR system, including
51 in the aortic regurgitation cases for which it was originally intended. As it is a crucial
52 issue, the landing of the locators at the cusps' nadirs cannot be based on tactile

53 feedback alone, but requires effective image-based guidance. Real-time three-
54 dimensional transesophageal echocardiography (3D TEE) may prove to be the best
55 suited modality – and even essential - to such scope.

56 3D TEE has demonstrated far greater accuracy and fineness than fluoroscopy and
57 angiography in the intraprocedural evaluation of the mechanism of aortic
58 regurgitation after deployment of a TAVR device. Real-time 3D TEE provides
59 information about the degree of elliptical expansion of the valve device, about the
60 anatomical relationship between the prosthetic and native commissures (anti-
61 anatomical expansion) [2]. All of these information can be discriminating in
62 intraprocedural decision-making. Also, TEE has been already proposed as the
63 primary imaging modality to guide the deployment of a TAVR device [3].

64 In transcatheter valve therapy, success is achieved through effectiveness and
65 reproducibility. The pathway towards success of this promising TAVR concept will
66 probably demand not only technological advancements (miniaturization of the 27-Fr
67 introducer, availability for retrograde delivery routes) but also full exploitation of
68 intraprocedural 3D TEE capabilities, and – most importantly – proof of reproducibility
69 in larger international trials. Cooperation with allied heart team professionals
70 (anesthesiologist, sonographer cardiologist) will be therefore essential.

71 In the end, this pathway further stimulates us to take advantage of the surgical
72 knowledge of cardiac anatomy, physiology and pathology, in order to continue being
73 the cutting edge in the innovation for valve therapy.

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92 Central Picture Legend

93 Authors' photo. Dr Anselmi (left) and Prof. Verhoye (right).

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