SIEMENS

White paper

3D rotational angiography and aortic valve guidance support accurate valve placement in TAVR.

Evidence predicts significant reduction in PVR and costs associated with its treatment.

Executive summary

Siemens *syngo* DynaCT Cardiac 3D rotational angiography and *syngo* Aortic ValveGuide aortic valve guidance software are effective in optimizing implant angles in transcatheter aortic valve replacements (TAVR). Excellent implant angles are significantly more likely to be associated with no paravalvular regurgitation (PVR) than non-excellent angles (41.3% vs. 21.6%, respectively, p=0.045) [1].

Study data published in EuroIntervention predict a significant reduction in PVR and the cost associated with its treatment when using *syngo* DynaCT Cardiac and *syngo* Aortic ValveGuide in TAVR procedures [1].

Transcatheter aortic valve replacements (TAVR) – now performed in over 40,000 patients worldwide – have been shown to improve hospitalization rates and mortality in patients deemed inoperable [2].

However, the success of the TAVR procedure is greatly dependent on the accurate alignment of the valve prosthesis in the aortic root. Complications of inaccurate valve positioning includes PVR which is increasingly recognized as an important contributor to mortality [3, 4].

PVR can lead to heart failure and a significant increase in cost for hospital readmission and subsequent treatment [5].

Given the adverse effects of PVR, the routine use of Siemens *syngo* DynaCT Cardiac and *syngo* Aortic ValveGuide in TAVR can offer significant clinical and financial benefits associated with a reduction in the rate of PVR.

Comparison of implant angle quality

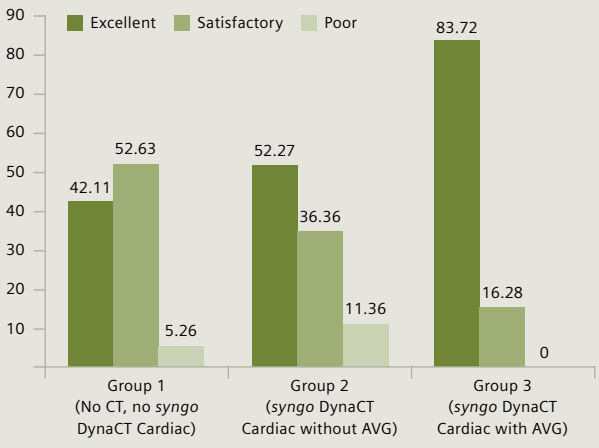

Figure 1. The *syngo* Aortic ValveGuide strategy (Group 3) was significantly more likely to lead to no PVR at all compared to patients in Group 2 or Group 1 (48.8% vs. 25.0% vs. 26.3% respectively, p=0.049) [1].

Answers for life.

Keywords

- *aortic valve guidance*
- *cost reduction*
- *paravalvular regurgitation*
- *re-admission rate*
- *3D rotational angiography*
- *TAVR*

Patients and methods

One hundred and nine patients were included in the *Poon, Walters et al.* study [1] and assigned to three groups based on the three strategies of implant angle generation:

Group 1 (n=19) no pre-procedural multislice CT (MSCT), no peri-procedural 3D rotational angiography, no *syngo* Aortic ValveGuide (AVG)
Group 2* (n=44) peri-procedural 3D rotational angiography (*syngo* DynaCT Cardiac), no AVG
Group 3** (n=43) peri-procedural 3D rotational angiography (*syngo* DynaCT Cardiac) and AVG

* Patients may or may not have had pre-procedural MSCT
** 29 patients in this group also had a pre-procedural MSCT

NB: Patients were excluded if a transcatheter heart valve (THV) was implanted within a previous THV or they received a THV within a failed prosthetic heart valve.

Definition of optimal angle

Categorical evaluation of the implanted THV was determined by two blinded independent radiographers based on previously utilized classification of excellent, satisfactory and poor [6]. "Excellent" implant angle quality was determined to be from perfectly aligned inferior valve struts, where the anterior inferior strut was up to half the height of a cell different from the posterior inferior strut. "Satisfactory" was where the gap between inferior struts was determined to be from half the height of a cell to a whole cell different. "Poor" implant angle was determined to be where the inferior struts were more than a whole cell different.

PVR assessment

Thirty-day prospectively collected transthoracic echocardiographic (TTE) follow-up data were assessed. One hundred TTEs were available from the 106 patients for analysis **(Figure 3)**. All TTEs were reported by experienced echocardiologists at a tertiary teaching centre, blinded to the implant angle prediction strategy utilised in each patient. PVR was categorically graded as none, mild, moderate, or severe as per VARC (Valve Academic Research Consortium) definitions.

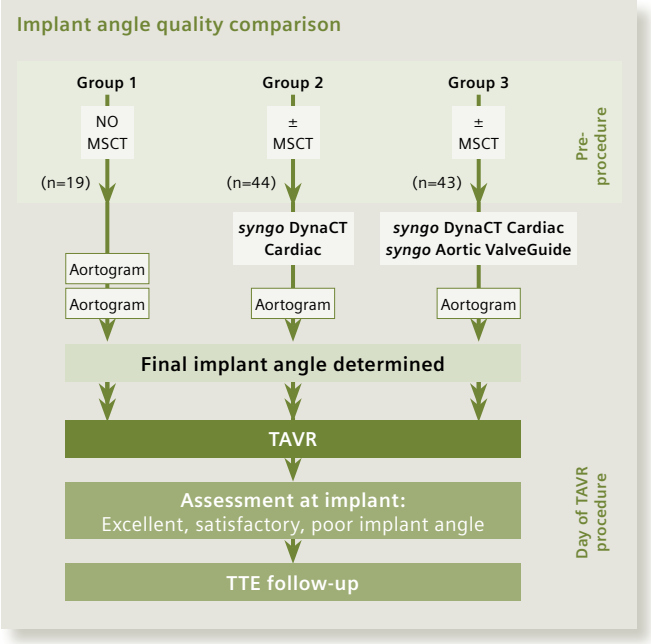

Figure 2. Implant angle quality comparison among the three groups.

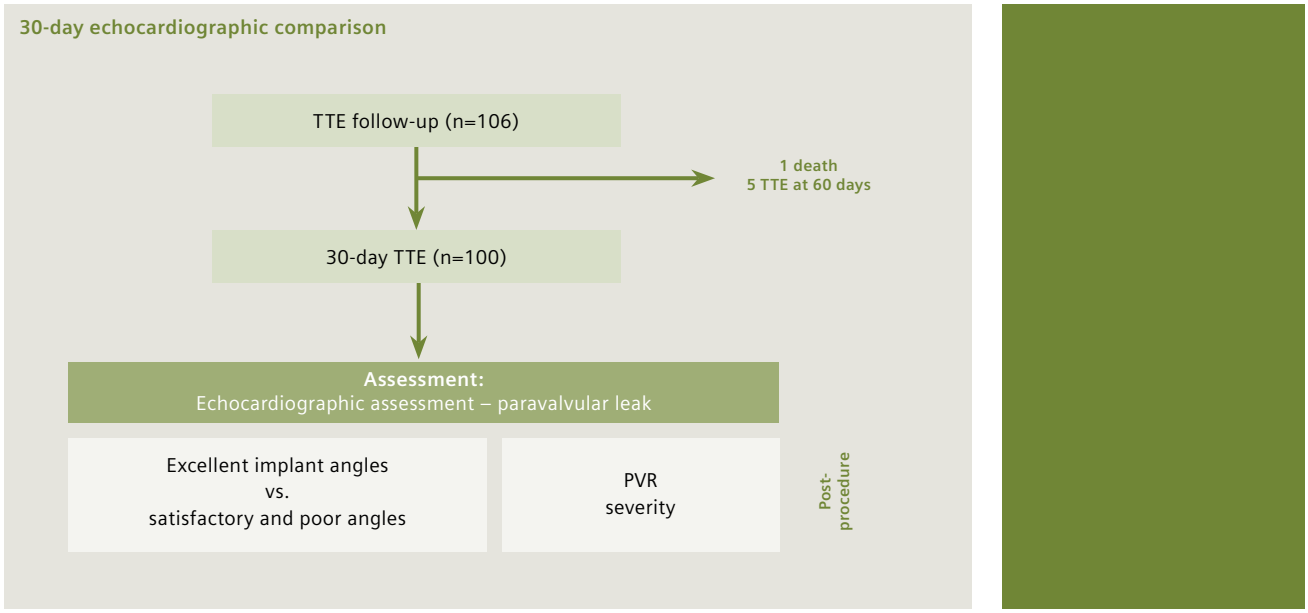

Figure 3. Impact of implant angle quality on PVR at 30-day follow-up.

Study methodology

Correlations were made between implant angle strategies, implant angle quality and PVR severity. Baseline characteristics and procedural data were compared among the three groups. Implant angles were compared between each strategy **(Figure 2)**. To establish the clinical impact of an implant angle, implant angle quality was correlated with the degree of PVR **(Figure 3)**.

Figure 4. *syngo* Aortic ValveGuide 3D model overlayed on live fluoroscopy guides heart value implantation.

3D image acquisition and aortic valve guidance software

3D reconstructions were obtained using Siemens *syngo* DynaCT Cardiac 3D rotational angiography and the *syngo* Aortic ValveGuide software. After X-ray image acquisition, the raw data was transferred onto a Siemens *syngo* Workplace for post processing with the Siemens *syngo* Aortic ValveGuide software.

These advanced software applications automatically detect the coronary artery ostia and the most inferior points of the aortic valvular sinuses, and align the sinuses in a linear position, all three cusps at equal distance to each other.

The integration of the Siemens *syngo* Aortic ValveGuide and the Artis zee angiography system allows the C-arm to be driven automatically to the displayed angle at the press of a button. This assures the optimal angle for accurate valve positioning.

Results

Procedures employing 3D rotational angiography (*syngo* DynaCT Cardiac) and aortic valve guidance software (*syngo* Aortic ValveGuide) were significantly more likely to provide an excellent implant angle compared to 3D rotational angiography alone or trial-and-error aortography (83.7% vs. 52.3% vs. 42.1%, respectively, p=0.001) **(Figure 1)**.

One hundred patients completed a 30-day TTE follow-up. 34% of patients had no PVR at 30 days. 66% had at least mild PVR, and 19% had at least moderate PVR **(Figure 7)**. The *syngo* Aortic ValveGuide strategy was significantly more likely to lead to no PVR at all, compared to patients in Group 2 or Group 1 (48.8% vs. 25.0% vs. 26.3%, respectively, p=0.045) **(Figure 5)**.

There was a strong correlation between the implant angle quality and PVR **(Figure 7)**. An excellent implant angle was significantly more likely to be associated with no PVR than satisfactory or poor implant angles (41.3% vs. 21.6%, respectively, p=0.045).

Figure 6. *syngo* Aortic ValveGuide provides fast 3D visualization of aortic root anatomy for effective procedure planning.

	Group 1 (No CT, no *syngo* DynaCT Cardiac)	Group 2 (*syngo* DynaCT Cardiac without AVG)	Group 3 (*syngo* DynaCT Cardiac with AVG)	*p*-value
Mean TTE days post implant	32.0	34.2	39.5	0.559
Preprocedural peak AV gradient (mmHg)	74.4	81.9	77.7	0.592
Post-procedural peak AV gradient (mmHg)	19.0	21.6	19.9	0.857
Preprocedural mean AV gradient (mmHg)	45.6	48.6	47.3	0.818
Post-procedural mean AV gradient (mmHg)	10.3	10.7	10.8	0.929
Preprocedural AVA (cm^2)	0.97	0.79	0.76	0.078
Post-procedural AVA (cm^2)	2.07	1.95	2.01	0.615
At least moderate PVR, n (%)	4 (21.1)	9 (20.5)	9 (20.9)	1.000
At least mild PVR, n (%)	14 (73.7)	33 (75.0)	22 (51.2)	0.049
No PVR, n (%)	5 (26.3)	11 (25.0)	12 (48.8)	0.049

Figure 5. Echocardiographic outcomes between different strategies.

	Excellent angle (n=63)	Satisfactory or poor angle (n=37)	*p*-value
No PVR, n (%)	26 (41.3)	8 (21.6)	0.045
At least mild PVR, n (%)	37 (58.7)	29 (78.4)	0.045
At least moderate PVR, n (%)	11 (17.5)	8 (21.6)	0.609
LVEF, %	58.6 %	58.6 %	0.99
Peak AV gradient (mmHg)	20.5	19.5	0.59
Mean AV gradient (mmHg)	11.1	10.4	0.52

Figure 7. Outcomes as determined by TTE 30 days post-intervention.

"Due to the increased accuracy of valve placement with Siemens syngo Aortic ValveGuide, this application has become an integral part of all TAVR cases within our hospital."

Darren Walters, M.D.,
Director of Cardiology,
Prince Charles Hospital
Brisbane, Australia

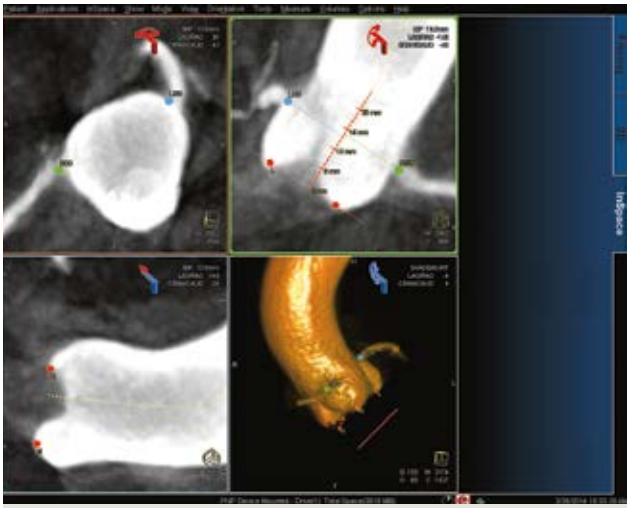

Figure 8. Aortic root segmentation result based on *syngo* DynaCT Cardiac 3D Volume.

Conclusion

The study done at The Prince Charles Hospital [1] indicates that an optimal implant angle is an critical factor in reducing PVR following TAVR.

Procedures employing 3D rotational angiography (*syngo* DynaCT Cardiac) and aortic valve guidance software (*syngo* Aortic ValveGuide) were significantly more likely to provide an excellent implant angle compared to 3D rotational angiography alone or trial-and-error aortography (83.7% vs. 52.3% vs. 42.1%, respectively, p=0.001).

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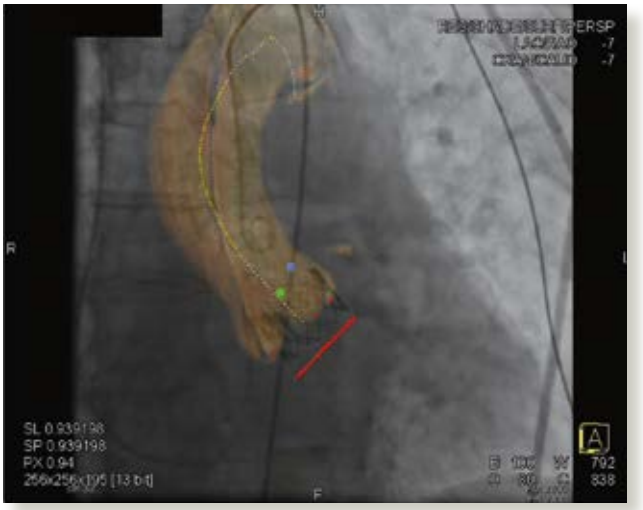

Figure 9. *syngo* Aortic ValveGuide overlays anatomical information and landmarks onto live fluoro for image guidance during valve positioning.

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Order No. A91AX-81401-12C1-7600 | Printed in Germany |
WS 05140.5 |

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