Predilatation Prior to Transcatheter Aortic Valve Implantation: Is it Still a Prerequisite?

Matteo Pagnesi,¹ Luca Baldetti,¹ Paolo Del Sole,¹ Antonio Mangieri,¹ Marco B. Ancona,¹ Damiano Regazzoli,¹
Nicola Buzzatti,² Francesco Giannini,¹ Antonio Colombo^{1,3} and Azeem Latib¹

1. Interventional Cardiology Unit, San Raffaele Scientific Institute, Milan, Italy; 2. Department of Cardiovascular and Thoracic Surgery, San Raffaele Scientific Institute, Milan, Italy; 3. Vita-Salute San Raffaele University, Milan, Italy

Abstract

Predilatation has been historically considered a mandatory step before transcatheter aortic valve implantation (TAVI) since it facilitates valve crossing and prosthesis delivery, ensures optimal valve expansion and improves hemodynamic stability during valve deployment. However, as a result of procedural evolution over time, direct TAVI (without pre-implantation balloon aortic valvuloplasty) has emerged as an interesting option to simplify the procedure and to avoid potential valvuloplasty-related complications. Several real-world retrospective studies and one small randomised study have shown that direct TAVI (with both self-expanding and balloon-expandable prostheses) is feasible, safe and associated with outcomes similar to standard TAVI with pre-implantation balloon aortic valvuloplasty. In the absence of high-quality, robust evidence, the current review aims to discuss the advantages and disadvantages of omitting predilatation prior to TAVI.

Keywords

Transcatheter aortic valve implantation, predilatation, direct transcatheter aortic valve implantation, balloon aortic valvuloplasty, aortic valve calcification, cerebral embolic risk, paravalvular leakage, postdilatation, permanent pacemaker.

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Correspondence: Azeem Latib, Interventional Cardiology Unit, San Raffaele Scientific Institute, Via Olgettina 60, 20132 Milan, Italy. E: alatib@gmail.com

Transcatheter aortic valve implantation (TAVI) has become an established treatment option for patients with severe, symptomatic aortic stenosis at high or intermediate surgical risk.^{1–4} From the very beginning of TAVI technology, valve preparation by performing pre-implantation balloon aortic valvuloplasty (pre-BAV) has been considered a necessary step to facilitate device implantation and ensure optimal valve expansion.⁵ However, as a result of procedural evolution over time and increasing operator experience, direct TAVI (without predilatation) has recently emerged as a new option to simplify the procedure and to avoid potential BAV-related complications (cerebrovascular events, conduction disturbances, severe acute aortic regurgitation and even annular rupture).^{6–9} After the first pioneering experience of Grube et al.,¹⁰ several observational studies and one small randomised study have evaluated procedural and clinical outcomes of TAVI with and without predilatation (*Table 1*). Therefore, this review aims to discuss the advantages of both direct TAVI and standard TAVI with pre-BAV, in light of the current published evidence.

Direct TAVI: Moving Toward a Simplified Approach

In an effort to obtain a more simplified and straightforward procedure, direct TAVI has increasingly been studied and performed (*Table 1*). Recent analysis of the UK TAVI Registry has shown a decreasing trend in the proportion of TAVI patients undergoing predilatation between 2007 and 2014; moreover, among centres with high experience (>200 TAVI performed), the rate of direct TAVI was around 50 %, decreasing to 11 % among centres with low experience (1–50 TAVI performed).¹¹ These findings confirm the interest of more experienced

operators in exploring a direct TAVI approach; simultaneously, they raise an interesting question regarding the potential (or demonstrated) advantages of removing predilatation.

Procedural Time and Contrast Use

As a logical result of removing one procedural step, this approach leads to shorter procedural time and lower total contrast volume use than TAVI with pre-BAV.^{12,13} This aspect may represent an interesting advantage for patients in whom a longer procedural time may be undesired, such as hemodynamically unstable patients, patients with severe left or right ventricular dysfunction or severe pulmonary hypertension (who, in addition, may not tolerate rapid pacing performed during balloon valvuloplasty). Furthermore, subjects at higher risk of contrast-induced nephropathy (e.g. those with pre-existing chronic kidney disease or diabetes mellitus) may benefit from lower contrast use during the procedure.¹⁴

Safety and Feasibility of Direct TAVI

The omission of one procedural step may be justified only if the simplified approach is demonstrated to be feasible, safe and not associated with adverse outcomes. The largest study exploring post-procedural outcomes after direct TAVI is the abovementioned UK TAVI Registry, that included 5,887 patients undergoing TAVI with vs without pre-BAV. In that study, direct TAVI was not associated with a higher rate of adverse short-term outcomes, especially when using the balloon-expandable SAPIEN (Edwards Lifesciences Inc., Irvine, CA) valve. For the self-expanding CoreValve (Medtronic, Minneapolis, MN) prosthesis, the use of predilatation was associated with lower odds of

Table 1: Studies Comparing the Outcomes of Patients Undergoing TAVI With and Without Predilatation

Study	Design	Study Population N	No pre-BAV	Pre-BAV	Age (years)	STS Score (%)	THV Used	Access Route	Procedural and 30-day Outcomes	Follow-up	Clinical Outcomes at Longest Follow-up
Ahn et al. 2016 ¹⁵	Randomised, single-centre	60	30	30	83 (range 58–93) no pre-BAV; 81 (range 42–91) pre-BAV	7 (range 1–13) no pre-BAV; 6 (range 2–17) pre-BAV	Sapien XT	TF n = 50 TA n = 10	Significantly lower number of rapid pacing in no pre-BAV group.	30 days	Similar rate of all-cause mortality, stroke, PVL and PPI in both groups.
Martin et al. 2017 ¹¹	Retrospective, multicentre	5,887	1,421	4,466	81.3 ± 7.5	4.9–5.0 ± 4.0–4.1	Sapien n = 3201 CoreValve n = 2467 Others n = 219	TF n = 4385 TA n = 952 Others n = 545	Significantly lower rate of PPI (adjusted OR 1.30 [95 % CI 1.04–1.62]) in no pre-BAV group. Similar rate of moderate–severe PVL, stroke, MI, VARC-2 early safety, and 30-day death in both groups. ^a	30 days	Similar rate of all-cause mortality in both groups. ^b
Bernardi et al. 2016 ¹⁶	Retrospective, multicentre	761	389	372	81.8 ± 7.1	10.2 ± 7.9	CoreValve n = 577 Sapien XT n = 184	TF n = 738 Non-TF n = 23	Significantly lower rate of 30-day new-onset persistent LBBB in no pre-BAV group (29.7 % vs 40.7 %; p = 0.006). Similar rate of PD, moderate–severe PVL, device success and 30-day outcomes (all-cause death, CV death, CVE, MI, PPI, VARC-2 safety endpoint) in both groups.	1 year	Similar rate of all-cause mortality, CV mortality, CVE, MI, PPI, moderate–severe PVL and VARC-2 efficacy endpoint in both groups. ^b
Abramowitz et al. 2016 ¹⁸	Retrospective, single-centre	513	121	392	82.5 ± 8.6	8.4 ± 5.2	Sapien n = 190 Sapien XT n = 323 Others n = 59	TF n = 423 TA n = 31 Others n = 59	Significantly lower fluoroscopy time (12.3 ± 5.1 vs 17.1 ± 8.4 min; months p < 0.001), contrast volume used (78.5 ± 37.1 vs 86.9 ± 41.1 mL; p = 0.048), and PVL rate (moderate–severe PVL 5.9 % vs. 0 %) in No pre-BAV group. Similar rate of PD, VARC-2 device success, and 30-day outcomes (death, CVE, MI, PPI) in both groups.	14.8 ± 9.9 months	Similar rate of all-cause mortality in both groups. ^b
Pagnesi et al. 2016 ¹⁷	Retrospective, single-centre	517	191	326	80.8 ± 7.5 no pre-BAV; 79.9 ± 7.4 pre-BAV	–	CoreValve n = 216 Evolut R n = 30 Sapien XT n = 210 Sapien 3 n = 61	TF	Significantly lower contrast volume used (134.1 ± 85.0 vs 155.0 ± 93.0 mL; p = 0.01) and higher rate of PD (35.6 % vs 21.5 %; p < 0.001), 30-day stroke (3.7 % vs 0.3 %; p < 0.01) and 30-day MACCE (7.3 % vs 3.4 %; p = 0.04) in no pre-BAV group. Similar rate of moderate–severe PVL, 30-day death, 30-day MI and 30-day PPI in both groups.	1 year	Similar rate of MACCE, all-cause mortality, MI and stroke in both groups. ^b

Table 1: Cont.

Study	Design	Study Population N	Age (years)	STS Score (%)	THV Used	Access Route	Procedural and 30-day Outcomes	Follow-up	Clinical Outcomes at Longest Follow-up
Abramowitz et al. 2016 ²⁷	Retrospective; single-centre	245	82.0 ± 7.8	6.3 ± 3.0	Sapien 3	TF n = 237 TA n = 3 Others n = 5	Significantly lower fluoroscopy time (13.0 ± 5.5 vs 16.2 ± 6.6 min; p < 0.01) and total contrast used (71.3 ± 31.0 vs 81.0 ± 36.4 mL; p = 0.03) in no pre-BAV group. Similar rate of PD, PVL, VARC-2 device success and 30-day outcomes (death, CVE, MI, PPI) in both groups.	8.1 ± 4.4 months	Similar rate of 1-year all-cause mortality in both groups. ^b
Spaziano et al. 2017 ²⁶	Retrospective; single-centre	281	82.7 ± 7.1	5.3 ± 3.5	Sapien 3	TF n = 232 Others n = 49	Similar fluoroscopy time, total contrast used and rate of PD, moderate-severe PVL and 30-day outcomes (death, stroke, MI, PPI) in both groups.	1 year	Similar rate of all-cause mortality in both groups.
Ferreira et al. 2016 ²⁷	Prospective; single-centre	204	83.1 ± 5.2	–	CoreValve n = 64 Edwards BEV n = 140	TF n = 204	Significantly lower procedural time (137.2 ± 66.9 vs 167.5 ± 83 min; p = 0.003) and contrast volume used (94.7 ± 35.9 vs 135.1 ± 51.1 mL; p < 0.001) in no pre-BAV group. Similar rate of PD, PVL, VARC-2 device success, PPI, stroke and 30-day death in both groups. ^b	Median: 21.4 months (IQR 10.0–38.0)	Similar rate of 1-year all-cause mortality in both groups. ^b
Toutouzas et al. 2016 ²⁸	Retrospective; multicentre	210	79 ± 17 no pre-BAV; 82 ± 6 pre-BAV	–	CoreValve	TF n = 194 Others n = 16	Significantly lower rate of moderate-severe PVL (7 % vs 33 %; p = 0.01) in no pre-BAV group. Similar rate of PD, VARC-2 device success, PPI and 30-day outcomes (all-cause and CV death, stroke, MI) in both groups.	1 year	Similar rate of all-cause mortality in both groups.
Kochman et al. 2014 ²⁹	Retrospective; single-centre	24	78.1 ± 8.4 no pre-BAV; 83.3 ± 3.7 pre-BAV	–	CoreValve	TF n = 18 Others n = 6	Similar rate of PD, moderate-severe PVL, VARC-2 device success and 30-day clinical outcomes (death, stroke, MI, PPI) in both groups.	1 year	Similar rate of all-cause mortality in both groups.
Hamm et al. 2017 ³⁰	Retrospective; single-centre	678	81.4 ± 5.3 no pre-BAV; 80.1 ± 5.6 pre-BAV	–	Sapien X n = 358 Sapien 3 n = 320	TF n = 373 TA n = 305	Significantly lower procedural time (56.7 ± 26.1 vs 85.6 ± 42.9 min; p < 0.001), fluoroscopy time (6.2 ± 3.9 vs 9.5 ± 5.7 min; p < 0.001), contrast volume used (85.4 ± 37.4 vs 131.9 ± 60.8 mL; p < 0.001), PD (16.5 % vs 25.1 %; p = 0.02), TAVI-in-TAVI (0 % vs 2.8 %; p = 0.005), 30-day all-cause death (2.9 % vs 6.8 %; p = 0.03), 30-day CV death (1.4 % vs 5.3 %; p = 0.01), 30-day VARC-2 safety endpoint (9 % vs 14.8 %; p = 0.04) in no pre-BAV group.	30 days	Lower rate of all-cause mortality, CV mortality and VARC-2 safety endpoint in no pre-BAV group. Similar rate of stroke and VARC-2 efficacy endpoint in both groups.

Similar rate of technical success, moderate-severe PVL, MI, PPI, VARC-2 device success, 30-day VARC-2 efficacy endpoint and 30-day stroke in both groups.									
Islas et al. 2015 ²³	Consecutive patients; single-centre	249	79	170	82 ± 5	–	Sapien XT n = 166 CoreValve n = 83	TF	Lower rate of all-cause mortality in no pre-BAV group.
Significantly lower procedural time (108.5 ± 35.6 vs 133.7 ± 46.9 min; p < 0.001) and 30-day death (2.5 % vs 11.8 %; p = 0.018) in no pre-BAV group.									
Similar total contrast used, PD, moderate-severe PVL, VARC-2 device success, stroke and PPI in both groups.									
Grube et al. 2011 ¹⁰	Retrospective; multicentre	186	60	126	80.1 ± 6.4 no pre-BAV; 81.9 ± 6.4 pre-BAV	–	CoreValve	–	Lower rate of all-cause mortality, CVE, MI and PPI in no pre-BAV group.
Higher rate of technical success (96.7 % vs 81.7 %) and lower rate of 30-day outcomes (mortality [6.7 % vs 14.3 %], MI [0 % vs 5.6 %], CVE [5.0 % vs 11.9 %] and PPI [11.7 % vs 27.8 %]) in no pre-BAV group.									
No severe PVL in both groups.									
Aggarwal et al. 2016 ⁴¹	Retrospective; single-centre	154	78	76	80.6 no pre-BAV; 82.2 pre-BAV	–	Sapien XT n = 111 Sapien 3 n = 43	TF	Similar rate of all-cause mortality, CVE and VARC-2 safety endpoint in both groups.
Significantly lower fluoroscopy time (13 vs 18.3 min; p = 0.01) and procedural time (104.9 vs 125.6 min; p < 0.001) in no pre-BAV group.									
Similar rate of PD, PVL, VARC-2 device success and 30-day outcomes (death, CVE, VARC-2 safety endpoint) in both groups.									
Kempfert et al. 2015 ⁴²	Prospective; single-centre	128	88	40	80 no pre-BAV; 80 pre-BAV	8.71 no pre-BAV; 7.22 pre-BAV	Sapien XT	TA	Similar rate of all-cause mortality in both groups. ^a
Significantly lower fluoroscopy time (306 [206–382] vs 341 [279–432] min; p = 0.04) in no pre-BAV group.									
Similar total contrast used, PD, moderate-severe PVL, CVE, PPI and 30-day death in both groups. ^b									
Wong et al. 2015 ⁴³	Retrospective; single-centre	121	50	71	84.3 ± 6.6 no pre-BAV; 84.4 ± 7.5 pre-BAV	9.4 ± 5.3 no pre-BAV; 8.5 ± 4.6 pre-BAV	Sapien	TF n = 71 TA n = 50	Similar rate of all-cause mortality, CV mortality, stroke, MI, PPI and VARC safety endpoint in both groups.
Similar rate of PD, PVL, VARC device success and 30-day outcomes (all-cause death, CV death, stroke, MI, PPI, VARC safety endpoint) in both groups.									
Fiorina et al. 2014 ⁴⁴	Retrospective; single-centre	110	55	45	83 ± 7 no pre-BAV; 83 ± 8 pre-BAV	10 ± 8 no pre-BAV; 7 ± 4 pre-BAV	CoreValve	TF n = 66 Others n = 34	Similar rate of all-cause mortality, CV mortality, MI, disabling stroke, PPI and VARC-2 safety endpoint in both groups.
Significantly lower rate of moderate-severe PVL (9 % vs 33 %; p = 0.02) and higher VARC-2 success rate (85 % vs 64 %; p = 0.014) in no pre-BAV group.									
Similar rate of PD and 30-day									

Table 1: Cont.

Study	Design	Study Population N	No pre-BAV	Pre-BAV	Age (years)	STS Score (%)	THV Used	Access Route	Procedural and 30-day Outcomes	Follow-up	Clinical Outcomes at Longest Follow-up
Bijuklic et al. 2015 ⁴¹	Consecutive patients; single-centre	87	55	32	82.9 ± 6.8 no pre-BAV; 83.8 ± 5.2 pre-BAV	–	Sapien XT n = 19 Sapien 3 n = 68	–	outcomes (all-cause death, CV death, MI, disabling stroke, PPI, VARC-2 safety endpoint) in both groups. Significantly lower total lesion volume at post-procedural cerebral DW-MRI (89.5 ± 128.2 vs 235.4 ± 331.4 mm ³ ; p = 0.01), procedural time (58.7 ± 31.6 vs 69.2 ± 41.7 min; p = 0.008), and contrast volume used (69.8 ± 22.5 vs 97.0 ± 50.8; p = 0.004) in no pre-BAV group. Similar rate of PVL and 30-day outcomes (death, MI, stroke) in both groups.	30 days	Similar rate of all-cause mortality, MI and stroke in both groups.
Bandali et al. 2016 ⁴⁵	Retrospective; single-centre	81	35	46	84 (95 % CI 82–86)	–	Sapien XT	TF	Significantly lower fluoroscopy time (9.3 [95 % CI 8.1–10.5] vs 11.2 [95 % CI 9.8–13.8] min; p = 0.03), radiation dose (18.0 [95 % CI 15.5–20.9] vs 24.9 [95 % CI 20.8–28.4] Gy*cm ² ; p = 0.01) and contrast volume used (80 [95 % CI 80–100] vs 110 [95 % CI 100–120] mL; p = 0.001) in no pre-BAV group. Similar rate of PD, PVL, procedural success and 30-day outcomes (death, CVE, MI, PPI) in both groups.	30 days	Similar rate of all-cause mortality, MI, CVE and PPI in both groups.
Van Linden et al. 2015 ⁴⁶	Retrospective; single-centre	66	49	17	83 ± 7	8 ± 5	Sapien 3	TA	Significantly lower radiation dose (32 ± 22 vs 75 ± 50 Gy*cm ² ; p < 0.001), total contrast used (50 ± 24 vs 75 ± 50 mL; p < 0.001) and PPI (12 % vs 41 %; p = 0.029) in no pre-BAV group. Similar rate of PD, moderate-severe PVL, CVE and 30-day death in both groups.	30 days	Similar rate of all-cause mortality in both groups.
Conradi et al. 2015 ⁴⁷	Retrospective; single-centre	52	26	26	81.3 ± 6.3 no pre-BAV; 81.7 ± 5.2 pre-BAV	6 ± 3 no pre-BAV; 5 ± 2 pre-BAV	Sapien XT n = 34 Sapien 3 n = 18	TF	Significantly lower fluoroscopy time (13.3 ± 5.8 vs 17.8 ± 6.9 min; p = 0.01) and total contrast used (118.7 ± 47.9 vs 153.0 ± 53.2 mL; p = 0.02) in no pre-BAV group. Similar procedural time, PD, PVL,	30 days	Similar rate of all-cause mortality, CV mortality and VARC-2 early safety endpoint.

VARC-2 device success, disabling stroke, MI, PPI, VARC-2 early safety endpoint and 30-day death in both groups.

Lange et al. 2014 ²¹	Retrospective; single-centre	237	123 ^c	114	82 (range 53–99)	9.1 (range 2.1–23.7)	CoreValve	TF	Significantly lower rate of PPI (15.4 % vs 27 %; $p = 0.042$) in moderate pre-BAV group.	–
Kim et al. 2017 ²⁴	Retrospective; multicentre	163	154	9	81.9 (IQR 77.5–85.0)	4.3 (IQR 3.0–6.5)	Sapien 3	TF	Significantly lower procedural time (34 [IQR 28.0–42.0] vs 50.5 [IQR 35.3–65.8] min) and fluoroscopy time (8.6 [IQR 6.6–12.9] vs 14.3 [IQR 10.8–16.9] min) in no pre-BAV group.	–
Conradi et al. 2014 ⁴⁸	Retrospective; single-centre	100	50	50	78 ± 8 no pre-BAV; 81 ± 7 pre-BAV	8 ± 7 no pre-BAV; 8 ± 5 pre-BAV	Sapien XT	TA	Significantly lower total contrast used (138 ± 68 vs 183 ± 78 mL; $p < 0.01$) in no pre-BAV group. Similar fluoroscopy time, procedural time, PD, moderate-severe PVL, VARC-2 device success, PPI, all-cause death, CV death, MI, stroke in both groups and VARC-2 early safety endpoint.	–
Mollmann et al. 2014 ⁴⁹	Retrospective; single-centre	56	26	30	81.9 ± 5.9	6.0 ± 2.9	Sapien XT	TF	Significantly lower radiation dose (42.0 [IQR 31.6–61.7] vs 56.6 [IQR 34.9–112.5] Gy*cm ² ; $p = 0.03$) and total contrast used (92.2 ± 20.5 vs 112 ± 31.0 mL; $p = 0.006$) in no pre-BAV group. Similar procedural time, fluoroscopy time, PD and moderate-severe PVL in both groups.	–

^aThis result was not confirmed after Bonferroni correction for multiple testing (adjusted OR 1.30 [95 % CI 0.91–1.86]). ^bResults derived from propensity score matched analysis. ^cModerate pre-BAV was performed in this group. BEV = balloon-expandable valve; CI = confidence interval; CV = cardiovascular; CVE = cerebrovascular event; IQR = interquartile range; LBBB = left bundle branch block; MACCE = major adverse cardiac and cerebrovascular event; MI = myocardial infarction; PD = postdilatation; PPI = permanent pacemaker implantation; pre-BAV = pre-implantation balloon aortic valvuloplasty; PVL = paravalvular leakage; STS = Society of Thoracic Surgeons; TA = transapical; TAVI = transcatheter aortic valve implantation; TF = transfemoral; THV = transcatheter heart valve; VARC-2 = Valve Academic Research Consortium-2.

valve dysfunction before correction for multiple testing; however, this finding was not confirmed after multiplicity correction.¹¹ These results are in line with a recent small prospective study that found similar early outcomes among 60 patients randomised to balloon-expandable TAVI (SAPIEN XT) with vs without predilatation.¹⁵ Moreover, recent large observational studies (including both balloon-expandable and self-expanding valves) have confirmed that direct TAVI is associated with similar mid-term clinical outcomes compared to TAVI with pre-BAV.^{16–18} These real-world data, along with recent meta-analyses,^{12,13,19} suggest that simplified TAVI without predilatation is feasible, safe and achieves comparable clinical outcomes to standard TAVI with predilatation, justifying future research in this field.

Conduction Disturbances

The omission of pre-BAV SAPIEN may theoretically reduce the iatrogenic damage to the conduction system, leading to a lower risk of conduction disturbances and, consequently, of new permanent pacemaker implantation (PPI) after TAVI. Indeed, new conduction disturbances may not only occur during valve implantation, but also during the predilatation step, especially in the case of high balloon/aortic annulus ratio.²⁰ Lange et al. have shown that moderate predilatation performed with smaller valvuloplasty balloons is associated with a reduced rate of PPI after CoreValve implantation; therefore, the authors proposed a two-hit model, where the first hit to the conduction system is given by a large valvuloplasty balloon and is usually insufficient to determine an advanced conduction disturbance, whereas the second hit is given by valve deployment and may eventually lead to the final damage requiring PPI.²¹ In line with these considerations, a recent analysis of the Brazilian Transcatheter Aortic Valve Replacement registry has reported that avoiding pre-BAV reduces the rate of new-onset persistent left bundle branch block after TAVI, particularly when implanting a CoreValve prosthesis.¹⁶ Although that study failed to demonstrate an association between omission of pre-BAV and reduction of PPI, recent meta-analyses and the large UK TAVI registry suggest a signal towards lower PPI rate with direct TAVI.^{11–13} Nevertheless, as the decision to perform pre-BAV was left to the operator's discretion in most published studies, a significant selection bias may have influenced these findings; only large randomised studies will clarify the impact of predilatation on conduction disturbances and PPI rate after TAVI.

Pre-procedural Imaging Planning

In the absence of definitive conclusions on the usefulness of predilatation during TAVI, the optimal strategy is probably to tailor the procedure to the individual patient. In daily practice, the interventional cardiologist should take into account all potential advantages of omitting pre-BAV and, therefore, avoiding its related complications (conduction disturbances, the risk of mobilising aortic debris potentially embolising to the brain, severe acute aortic regurgitation leading to haemodynamic compromise, and even annular rupture).^{6–9,22} However, in some patients predilatation may still be useful to optimise valve implantation and should be considered when planning the procedure. In this context, pre-procedural imaging techniques may be pivotal in deciding whether to predilate or not before TAVI. A recent study evaluated the usefulness of transoesophageal echocardiography (TEE) to select ideal candidates for direct TAVI with both balloon-expandable (SAPIEN XT) and self-expanding (CoreValve) prostheses. Among patients fulfilling all the proposed TEE criteria (valve area >0.4 cm²; central orifice; absence of severe valve calcification; mobility of aortic cusps not severely restricted; no left ventricular outflow tract

calcification; absence of calcium nodules in the landing zone; absence of severe aortic regurgitation), TAVI without pre-BAV was performed with a high rate of success and low rates of postdilatation, paravalvular aortic regurgitation and PPI implantation.²³ Combining anatomical and functional information obtained with a multimodality approach (TEE and multidetector computed tomography [MDCT]) could represent the ideal strategy to identify the subset of patients who can safely undergo simplified TAVI without predilatation.

TAVI with Predilatation: Potential Advantages of 'Preparing the Ground'

A main concern regarding the omission of predilatation is the risk of technical challenges during TAVI. Pre-BAV may facilitate valve crossing and delivery of the prosthesis across the stenotic valve (especially in patients with very small aortic valve area), ensure optimal valve expansion (by reducing radial counterforces) and improve haemodynamic stability during valve deployment. Interestingly, a range of technical difficulties has been reported when adopting a direct TAVI approach, including haemodynamic instability during device positioning in severely stenotic valves, severe underexpansion of the prosthesis in heavily calcified valves, inability to cross the valve, trapping of the prosthesis inside the left ventricle and coaxiality issues.¹⁶ Furthermore, as already mentioned, the UK TAVI registry showed a signal towards increased valve dysfunction among patients receiving a CoreValve prosthesis without pre-BAV (a finding that was, however, not confirmed after Bonferroni correction for multiple testing).¹¹ Although bailout predilatation may represent an option to overcome pre-implantation technical issues,^{16,24,25} careful selection of patients needing pre-BAV before TAVI is advisable to avoid the risk of severe procedural complications. Pre-procedural planning by means of combined imaging techniques (TEE and MDCT) allows the identification of basic anatomical features in which a standard TAVI approach (with predilatation) should be considered, such as severe or asymmetric aortic valve calcification, small aortic valve area (<0.5 cm²), horizontal aorta (especially when implanting self-expanding prostheses) or bicuspid aortic valve anatomy.^{18,23,26–29}

Pre-BAV may be very helpful also in situations where prosthesis sizing is not completely established or the potential risk of coronary obstruction requires further assessment (especially when coronary artery takeoffs are low).³⁰ As MDCT has become the standard technique for valve sizing and coronary ostia evaluation before TAVI, these two indications are limited to a very low number of patients in the contemporary TAVI era; nonetheless, pre-BAV represents a rescue option for patients in whom MDCT cannot be performed or is not conclusive.

Cerebral Embolic Risk

One of the proposed advantages of direct TAVI is to avoid the risk of debris embolisation during balloon valvuloplasty, potentially resulting in a lower rate of cerebrovascular events.¹⁰ However, a recent study evaluating cerebral ischemic lesions after TAVI has suggested the opposite idea. Bjuklic et al. have evaluated covert brain lesions detected by diffusion-weighted magnetic resonance imaging after TAVI in patients undergoing balloon-expandable valve (SAPIEN XT or SAPIEN 3) implantation with or without predilatation. The total lesion volume of cerebral ischemic lesions was significantly higher among patients undergoing direct TAVI; the incidence and number of cerebral lesions were only numerically (not significantly) higher in the direct TAVI group.³¹ These results seem in line with a recent study reporting

Figure 1: Proposed Decision-making Algorithm for the Selection of Patients who can be Considered for Direct TAVI (Without Predilatation)

The flowchart includes clinical and imaging factors that may help in deciding whether or not to perform predilatation prior to TAVI. *Especially if balloon-expandable valve implantation is planned; **especially if self-expanding valve implantation is planned. AA = aortic angulation; AR = aortic regurgitation; AVA = aortic valve area; CKD = chronic kidney disease; COPD = chronic obstructive pulmonary disease; GFR = glomerular filtration rate; LVOT = left ventricular outflow tract; PASP = pulmonary artery systolic pressure; TAVI = transcatheter aortic valve implantation.

a higher 30-day overt stroke rate in patients undergoing direct TAVI, especially when implanting self-expanding (CoreValve or Evolut R) prostheses; however, this finding was not confirmed after propensity score matching.¹⁷ The idea of a higher risk of cerebral damage when performing TAVI without predilatation seems counterintuitive as balloon dilatation of the aortic valve may *per se* be complicated by post-procedural stroke^{6,7,22,32} and one may suppose that pre-BAV before TAVI may confer an additive risk of neurological events. Conversely, it can be speculated that balloon inflation fragments calcific debris present on a heavily degenerated and diseased aortic valve, stabilises such debris through a homogeneous apposition onto aortic leaflets and the ascending aortic wall, and reduces the size of pieces that embolise during subsequent valve implantation. Studies evaluating transcranial Doppler-detected cerebral embolic load during TAVI have shown that only a limited number of high-intensity transient signals (a surrogate for microembolisation) occur during pre-BAV, while prosthesis positioning and deployment are the two phases associated with the highest embolic load,^{33–35} indirectly suggesting that the predilatation step does not significantly increase the cerebral embolic risk of the TAVI procedure. However, most published studies have shown a similar rate of clinical strokes in TAVI with and without pre-BAV^{11,12,15} and the reason for the higher risk of covert cerebral injury reported in the study of Bjuklic et al. remains completely speculative.³¹ Only future large, dedicated studies will definitively clarify the impact of predilatation on the risk of overt/covert cerebral injury

after TAVI, especially if investigating the cerebral embolic load during all procedural steps.

Paravalvular Leakage

An expected limitation of direct TAVI is the risk of suboptimal valve expansion, potentially resulting in higher incidence and severity of residual paravalvular leakage (PVL) after the procedure. The occurrence of PVL immediately after valve implantation may lead to an increased need for postdilatation, a step that may theoretically impair prosthesis durability and that has been specifically associated with a higher risk of cerebrovascular events.^{36–38} In line with these considerations, a recent study has reported a higher rate of postdilatation in patients undergoing direct transfemoral TAVI,¹⁷ a finding that was confirmed in a meta-analysis.¹² Unfortunately, the largest available study did not evaluate the need for postdilatation,¹¹ preventing us from drawing more robust conclusions on this procedural aspect. With respect to the impact of direct TAVI on significant PVL, most published studies have reported similar rates of residual moderate or severe PVL after TAVI with or without predilatation (Table 1), including the large UK TAVI registry.¹¹ Interestingly, two meta-analyses have suggested a reduced risk of moderate or severe PVL with direct TAVI (a result that was, however, not confirmed in a subanalysis evaluating only transfemoral TAVI).^{12,13} Although this counterintuitive finding seems to suggest an improved valve positioning with direct TAVI, the retrospective nature of the studies included may have determined a relevant selection

bias. The choice of a predilatation strategy was left to the operators' discretion, therefore it is likely that direct TAVI was performed more frequently in patients with favourable anatomical characteristics and the absence of severe or asymmetric aortic valve calcification. As the quantity and asymmetry of aortic valve calcification predict the severity of post-procedural PVL,^{39–44} this selection bias is of paramount importance. Moreover, other confounders such as device improvements and increasing the operator's experience may have influenced these analyses. In the absence of high-quality, robust evidence on the incidence and severity of PVL after direct TAVI, definitive conclusions cannot be drawn; however, as PVL negatively affects clinical outcomes after TAVI,^{3,45–54} future large, randomised studies are needed to further address the risk of PVL when performing TAVI with or without predilatation.

'Moderate' Predilatation

An interesting option that has been recently proposed is performing TAVI with a moderate predilatation, i.e. prior balloon valvuloplasty with a smaller balloon size. This approach could preserve the advantages of pre-BAV in 'preparing the ground' before valve implantation, avoiding the risks of predilatation with a standard or larger balloon. As already mentioned, Lange et al. have shown that moderate predilatation (use of valvuloplasty balloons with ≤ 23 mm diameter) reduces the rate of PPI in patients undergoing TAVI with the CoreValve prosthesis, without affecting procedural success.²¹ Although the use of smaller balloons may conceivably reduce the iatrogenic damage to the conduction system, a concern regarding moderate pre-BAV is impaired valve expansion, mainly when using self-expanding devices and in cases of severe valve calcification. Moreover, recent studies have reported similar procedural success and clinical outcomes after TAVI with moderate predilatation (average balloon diameter of 15–16 mm; mean balloon diameter/MDCCT mean annulus diameter ratio of 0.62–0.65)

compared with direct TAVI with balloon-expandable valves.^{18,27} Of note, valve repositioning during implantation of newer self-expanding devices could arguably represent a form of mild predilatation; however, the relative role of this step with respect to pre-BAV is currently unknown. Future large, dedicated studies will better evaluate the potential advantages of moderate pre-BAV over standard or larger pre-BAV or direct TAVI in terms of procedural and clinical outcomes.

Conclusion

A growing interest in direct TAVI (without predilatation) has emerged during the last few years in an effort to obtain a more simplified procedure and to avoid the potential complications associated with pre-BAV. Recent real-world observational experiences and a small randomised study suggest that direct TAVI is safe, feasible and associated with outcomes similar to standard TAVI with pre-BAV (*Table 1*). In the absence of strong available evidence, several clinical and anatomical characteristics may help the interventional cardiologist in deciding whether or not to predilate before TAVI (*Figure 1*). However, future studies are needed to deeply investigate the safety and outcomes of direct TAVI and to identify the right subset of patients who can safely undergo this simplified approach. The results of ongoing dedicated randomised trials (The preDilatation in tRanscatheter aortic Valve implanTation Trial [DIRECT], NCT02448927; Implantation of the Transcatheter Aortic Prosthesis SAPIEN 3 With or Without Prior Balloon Predilatation [DIRECTAVI], NCT02729519; Transcatheter Aortic Valve Implantation Without Predilation [SIMPLIFY TAVI], NCT01539746) and prospective multicentre registries (Transfemoral Transcatheter Aortic Valve Implantation With or Without Predilation of the Aortic Valve [EASE-IT TF],⁵⁵ NCT02760771; Balloon Expandable Transcatheter Aortic Valve Implantation Without Predilation of the Aortic Valve [EASE-IT],⁵⁶ NCT02127580) will provide additional evidence on these unresolved issues. ■

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