Prosthesis Infolding Incidence and Short-Term Outcomes in Transcatheter Aortic Valve Implantation Using Evolut Self-Expandable Device: A Multicenter Study

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Transcatheter aortic valve implantation (TAVI) is an established treatment strategy in aortic valve disease. Infolding, as a nonuniform expansion of the prosthesis leading to introflection of part of the device circumference, is a complication specific to self-expandable prostheses. The aim of the study is to determine incidence, predictors, treatment strategy, and outcomes of infolding during Medtronic Evolut TAVI (Minneapolis, MN, US). Between January 2018 and March 2022, all patients treated with Evolut TAVI were included in a multicenter observational retrospective study. According to the occurrence of infolding, the enrolled cohort was divided into 2 groups; periprocedural characteristics and 30-day outcomes were compared. A total of 1,470 patients were included; 23 infolding cases (1.6%) were detected. Preprocedural imaging showed larger aortic anatomy and greater calcium burden in the infolding group. Infolding occurred mostly with Evolut Pro + and size 34 mm and was diagnosed before full prosthesis release in 78.3%. The rate of moderate-to-severe paravalvular regurgitation was higher in the infolding group (21.7% vs 1.9%, p <0.001). Short-term follow-up showed greater all-cause and cardiovascular mortality (respectively, 4.3% vs 0.7% and 4.3% vs 0.6%, p <0.05) and higher rate of pacemaker implantation (33.3% vs 15.7%, p = 0.042) in case of infolding. High right cusp calcium score and resheathing maneuvers were independent predictors of infolding. In conclusion, prosthesis infolding is a TAVI complication burdened by worse cardiovascular outcomes. Prompt intraprocedural infolding diagnosis is pivotal, especially in case of great native valve calcium burden and resheathing maneuvers, to safely overcome this complication by prosthesis recapture or postdilation. **(Am J Cardiol 2024;221:102−109)**

Keywords: infolding, outcomes, transcatheter aortic valve implantation, VARC-3

Since the first-in-human procedure performed in 2002, transcatheter aortic valve implantation (TAVI) has become a valid treatment strategy for symptomatic severe aortic stenosis. The clinical indication for TAVI has been extended to all the surgical risk classes, encompassing even bicuspid anatomy and pure aortic regurgitation.[1,2] The growing experience of TAVI operators and the technologic progress to overcome possible complications rendered the procedure as effective as surgical aortic valve replacement.[3,4] Although the rate of periprocedural complications is low and comparable in self-expandable and balloon-expandable prostheses, there is growing evidence of unusual complications that may be prosthesis-specific. In particular, infolding may occur during self-expandable valve deployment.[5–9] Infolding is described as a nonuniform expansion of the prosthesis during the delivery phase, leading to an introflection of part of the device circumference along both the inflow and outflow tract (Figure 1); this altered conformation is associated with valve dysfunction and severe paravalvular regurgitation (PVR). Since a proper analysis about the clinical impact of infolding is lacking in the literature, we designed this multicenter study with the aim of examining in depth the incidence, predictors, treatment strategies, and outcomes of this underreported complication of the most used self-expandable TAVI prosthesis, the Medtronic Evolut (Minneapolis, MN, US).

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See page 108 for Declaration of Competing Interest.

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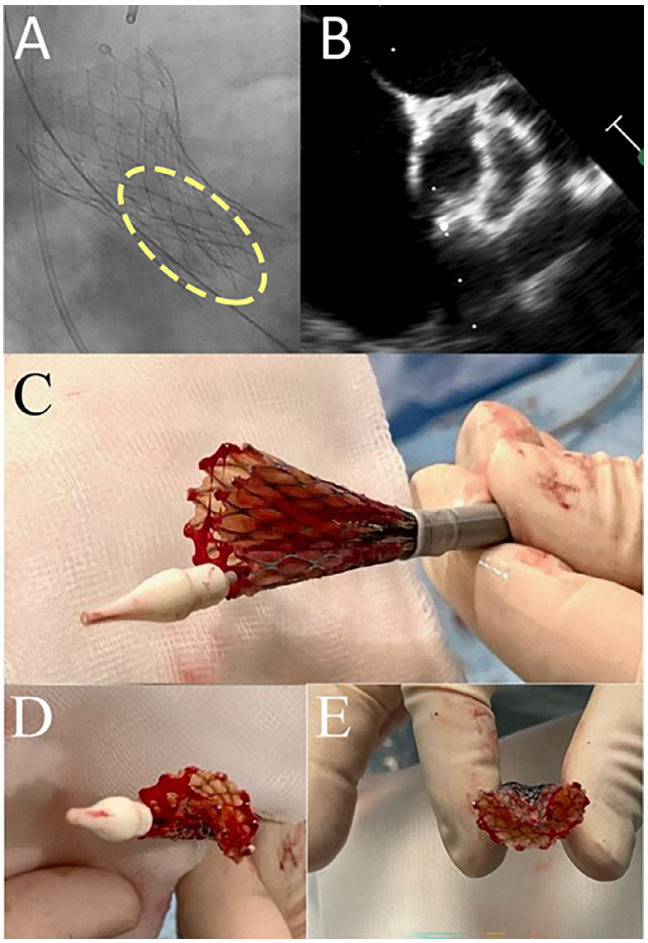

Figure 1. Transcatheter prosthesis infolding. Fluoroscopic evidence of prosthesis infolding after delivery as shown by the presence of a "vertical line" along inflow and outflow tract due to frame overlap in the yellow dotted line (*A*); midesophageal short-axis view of infolded prosthesis with the typical half-moon shape (*B*). In vivo evidence of a retrieved infolded prosthesis (*C*–*E*).

Methods

This study is an observational retrospective multicenter study (HartCentrum ZNA Middelheim, Antwerp, Belgium; Heart Center Rigshospitalet, Copenhagen, Denmark; Universitatsklinikum, Dusseldorf, Germany; Oulu University Hospital, Oulu, Finland; University of Verona, Verona, Italy). All consecutive patients who underwent TAVI using Medtronic Evolut prosthesis (R, Pro, Pro+) for severe aortic stenosis (including native valve disease or failed surgical bioprosthesis) or pure aortic regurgitation between January 2018 and March 2022 were included in the study. A dedicated database was filled in using institutional registry derived data.

The enrolled cohort was divided into 2 groups according to the occurrence of infolding during the procedure.

Infolding was defined as a non-uniform expansion of the prosthesis during the delivery phase leading to an introflection of part of the device circumference along both the inflow and outflow tract; the diagnosis was performed using fluoroscopy or intraprocedural transesophageal echocardiography (TEE) when available. Fluoroscopic diagnosis of infolding was performed in case of a reduced transverse prosthesis diameter associated with a string sign, defined as a vertical line due to frame overlap (Figure 1). Ultrasound diagnosis of infolding was made by the observation of valve frame segmentary invagination, namely, "Pac-man sign," in midesophageal short-axis view (Figure 1). Prosthesis infolding rate and interventional treatments were evaluated. Predictors of infolding and 30-day outcomes were also analyzed.

Additional methods information is available in the Supplementary Methods section.[10,11]

Results

The registry included 1,470 consecutive patients who underwent TAVI using Medtronic Evolut prosthesis at the 5 centers; 23 cases (1.6%) of infolding were detected.

Clinical assessment and history are listed in Supplementary Table 1. The overall mean age was 81 ± 6 years; a greater prevalence of men in the infolding group was observed (78.3% vs 53.5%, p = 0.018). No statistically significant differences were observed between the control and infolding groups regarding cardiovascular history and risk factors. A diagnosis of bicuspid aortic valve was non-significantly more prevalent in the infolding group (22.7% vs 11.3%). The overall cohort surgical risk evaluated by The Society of Thoracic Surgeons Predicted Risk of Mortality (STS-PROM) and EuroSCORE II was intermediate to low. In the infolding group, there were no cases of pure aortic regurgitation as indication for TAVI. The preoperative echocardiographic assessment described an overall preserved systolic left ventricular function and a lower rate of low-flow low-gradient aortic stenosis in the infolding group: consequently, transvalvular gradient and velocity were greater. Furthermore, the estimated aortic valve area was smaller in the infolding group (Supplementary Table 2).

The preoperative multislice computed tomography-derived calcium analysis is presented in Table 1. The left ventricle outflow tract total calcium burden was significantly lower in the control group (108.6 mm^3 ± 106.1 vs 87.5 mm^3 ± 175.4, p = 0.029), without a specific outflow circumferential distribution; in addition, the aortic valve total calcium burden was greater in the infolding group (1,807.8 mm^3 ± 2,374 vs 933.8 mm^3 ± 1,252, p = 0.016) with greater calcium volume involving right (661 mm^3 ± 990.8 vs 269.8 mm^3 ± 391.4, p = 0.003) and left (571.5 mm^3 ± 796.7 vs 313.2 mm^3 ± 568.4) coronary artery cusp (Figure 2). The sino-tubular junction and the sinuses of Valsalva were larger in the infolding group; moreover, the annulus measurements were larger in the infolding group for both the direct diameter estimation and the area/perimeter-derived diameter estimation. The shape of the annulus was comparable in the 2 groups as indicated by similar incidence of ellipticity (Supplementary Table 3).

In the infolding group, we observed an increased implantation rate of Evolut Pro+ (21.8% vs 11%, p = 0.011) and size 34 mm (56.5% vs 28.3%, p = 0.029), as shown in Figure 3. Furthermore, owing to greater calcium valve burden, predilation was performed more frequently in the infolding group (65.2% vs 42%, p = 0.025, Table 2). Positioning error requiring resheathing of the prosthesis was

Table 1
Pre-operative CT scan-derived aortic calcium burden

	Observation (n)	Overall (n=1470)	Control (n=1447)	Infolding (n=23)	p-value
Calcification threshold (HU), mean ± SD	979	538.9±198.5	538.4±198.4	569.3±210.5	0.367
Aortic valve total calcium scoring (mm^3), mean±SD	1038	945.6±1275	933.8±1252	1807.8±2374	**0.016**
Non-coronary cusp calcium scoring (mm^3), mean±SD	1028	330.1±389.9	326.7±384.1	575.2±666.9	0.086
Right coronary cusp calcium scoring (mm^3), mean±SD	1028	275.1±407	269.8±391.4	661±990.8	**0.003**
Left coronary cusp calcium scoring (mm^3), mean±SD	1025	316.7±572.4	313.2±568.4	571.5±796.7	**0.011**
LVOT total calcium scoring (mm^3), mean±SD	704	87.8±174.5	87.5±175.4	108.6±106.1	**0.029**
Non-coronary LVOT calcium scoring (mm^3), mean±SD	434	57.2±100.1	56.7±99.9	87.8±112.2	0.508
Right coronary LVOT calcium scoring (mm^3), mean±SD	267	17.1±32.4	17.1±32.7	15.8±19.2	0.818
Left coronary LVOT calcium scoring (mm^3), mean±SD	467	63.2±127.1	63.5±128.1	49.3±34.7	0.234

Values are mean ± SD or n (%).
LVOT = left ventricle outflow tract.

3 times as frequent in the infolding group (77.3% vs 26%, p <0.001), with an average of 2 attempts. The rate of postdilation was predictably higher in the infolding group (45.5% vs 19.8%, p = 0.003) as part of the interventional therapy. Thus, procedural time and fluoroscopy time were significantly shorter in the control group. Most of the cases of infolding were diagnosed before full prosthesis release (78.3%), as listed in Supplementary Table 4. The interventional therapy to overcome prosthesis infolding is indicated in Figure 4: 11 of 23 cases were treated with recapturing and subsequent change of the prosthesis; the remaining infolding cases were treated mainly by balloon postdilation (Supplementary Video 1). One case required the implantation of a balloon-expandable prosthesis inside the infolded valve owing to ineffective postdilation, and 1 case was treated with surgery because of high risk of aortic root rupture after postdilation with larger balloon in a heavily calcified native valve. Case-by-case highlights of prosthesis infolding management are listed in Supplementary Table 5.

Intraprocedural hemodynamics and complication are listed in Table 2. As expected, the rate of moderate-to-severe PVR was significantly higher in the infolding group (21.7% vs 1.9%, p <0.001). In the infolding group, the rates of hemodynamic deterioration and inotropes use were higher, and 1 case needed conversion to surgery (4.3% vs 0%, p = 0.001). Intraprocedural stroke/transient ischemic attack (4.3% vs 0.2%, p <0.001) and onset of advanced atrio-ventricular block (31.8% vs 12.1%, p = 0.005) were more frequent in the infolding group.

On univariate logistic regression analysis, the predictors of prosthesis infolding were larger prosthesis size, native valve predilation, need for prosthesis resheathing, aortic valve calcium burden, and sino-tubular junction and annulus size (Supplementary Table 6). Moreover, multivariable stepwise logistic regression analysis revealed that the independent predictors of infolding were the need for resheathing (odds ratio 0.039 [0.017-0.060], p <0.001) and right cusp calcium score >409.5 mm^3 (odds ratio 0.031 [0.005-0.058], p <0.05).

Data regarding the outcomes at 30-day follow-up are listed in Table 3. The occurrence of prosthesis infolding is burdened by greater all-cause and cardiovascular mortality (respectively, 4.3% vs 0.7% and 4.3% vs 0.6%, p <0.05). In addition, major adverse cardiac and cerebrovascular events at follow-up were observed more frequently in the infolding group (13% vs 1.5%, p <0.001), driven by cardiovascular death, mild stroke and fatal bleeding. Concerning the function of the prosthesis, residual mild PVR was observed

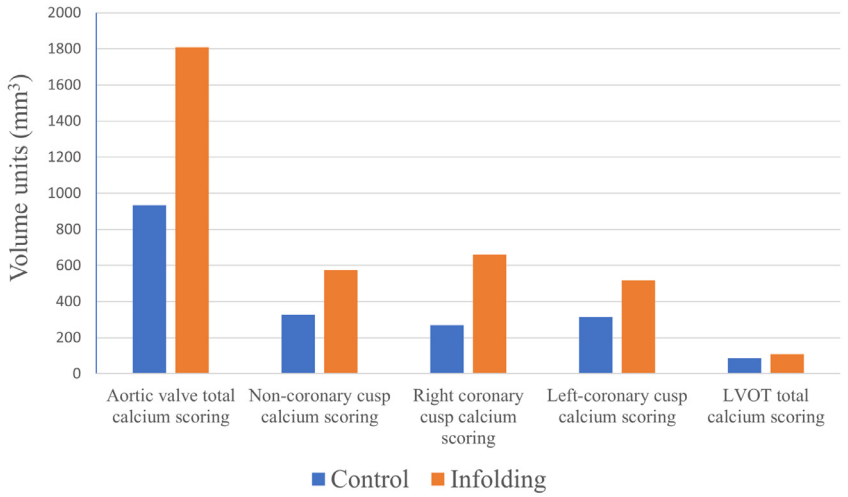

Figure 2. Multislice computed tomography-derived calcium burden comparison between control group and infolding group. The total calcium burden was significantly greater in the infolding group for both left ventricle outflow tract and aortic valve with large calcium volume involving right and left coronary artery cusp. All the comparisons were statistically significant (p <0.05) except for non−coronary artery cusp calcium score.

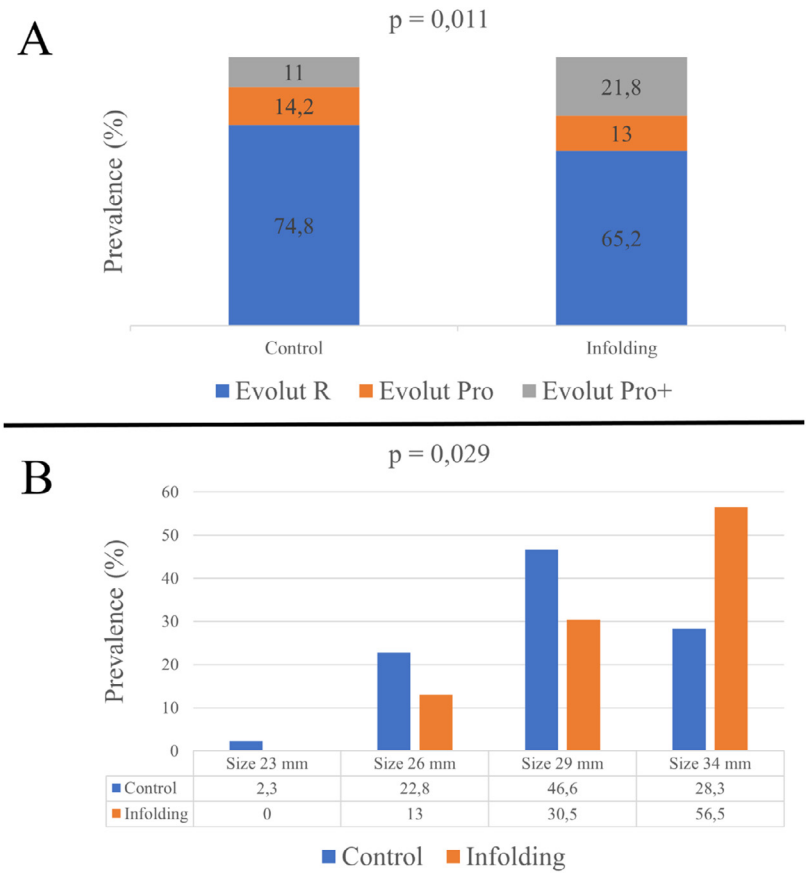

Figure 3. Self-expandable prosthesis implantation model and size. The prevalence of the Evolut Pro+ prosthesis model has nearly doubled in the infolding group (*A*). The 34-mm size prosthesis was the most prevalent in the infolding group; no infolding was observed using the 23-mm size prosthesis (*B*).

Table 2
Prosthesis-related delivery characteristics

	Observation (n)	Overall (n=1470)	Control (n=1447)	Infolding (n=23)	p-value
THV/annulus ratio (%), mean±SD	1396	19.98±10.51	19.99±10.56	19.05±6.8	0.676
Pre-dilation, n (%)	1469	622 (42.3)	607 (42)	15 (65.2)	**0.025**
Need for resheathing, n (%)	1192	321 (26.9)	304 (26)	17 (77.3)	**< 0.001**
Number of resheathing (n), mean±SD	908	0.34±0.7	0.3±0.6	1.9±1.4	**< 0.001**
Post-dilation, n (%)	1460	295 (20.2)	285 (19.8)	10 (45.5)	**0.003**
Fluoroscopy time (min), mean±SD	1312	17.5±8.7	17.3±8.5	28.5±14.9	**< 0.001**
Procedural time (min), mean±SD	1267	72.2±30.7	71.8±30.3	98.9±42.8	**< 0.001**
Femoral access for valve delivery, n (%)	1470	1459 (99.3)	1436 (99.2)	23 (100)	0.916
Intraprocedural moderate-to-severe PVR, n (%)	1470	32 (2.2)	27 (1.9)	5 (21.7)	**< 0.001**
Intraprocedural shock, n (%)	1470	9 (0.6)	8 (0.6)	1 (4.3)	**0.021**
Intraprocedural inotropes, n (%)	1470	23 (1.6)	20 (1.4)	3 (13)	**< 0.001**
Intraprocedural tamponade, n (%)	1470	3 (0.2)	3 (0.2)	0 (0)	0.827
Intraprocedural stroke/TIA, n (%)	1469	4 (0.3)	3 (0.2)	1 (4.3)	**< 0.001**
Intraprocedural annulus rupture, n (%)	1470	1 (0.1)	1 (0.1)	0 (0)	0.900
Intraprocedural conversion to surgery, n (%)	1470	5 (0.3)	4 (0.3)	1 (4.3)	**0.001**
Intraprocedural device dislocation, n (%)	1470	10 (0.7)	10 (0.7)	0 (0)	0.689
Intraprocedural aortic dissection, n (%)	1470	2 (0.1)	2 (0.1)	0 (0)	0.858
Intraprocedural left ventricle perforation, n (%)	1470	2 (0.1)	1 (0.1)	1 (4.3)	**< 0.001**
Intraprocedural coronary obstruction, n (%)	1470	3 (0.2)	3 (0.3)	0 (0)	0.827
Intraprocedural vascular complication, n (%)	1470	76 (5.2)	74 (5.1)	2 (8.7)	0.442
New onset left bundle branch block, n (%)	1470	285 (19.4)	281 (19.4)	4 (17.4)	0.807
New onset AV block > I degree, n (%)	1376	171 (12.4)	164 (12.1)	7 (31.8)	**0.005**

Values are mean ± SD or n (%). THV/annulus ratio was calculated as the percentage ratio of the difference between valve perimeter and annulus perimeter and the annulus perimeter.

AV = atrio-ventricular; PVR = para-valvular regurgitation; THV = transcatheter heart valve; TIA = transient ischemic attack.

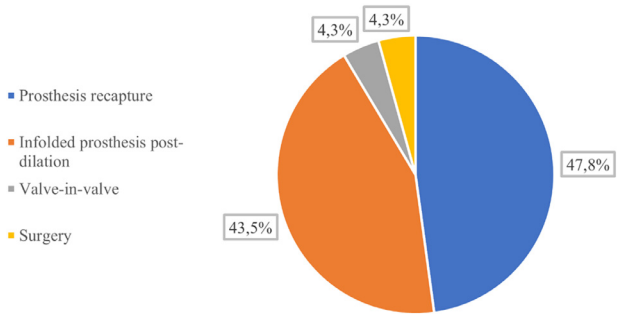

Figure 4. Interventional therapy to overcome prosthesis infolding. Most of the infolding cases were treated with recapture before full prosthesis release or postdilation after full prosthesis release. Valve-in-valve implantation and cardiac surgery were the bail-out strategies.

more frequently in case of infolding (69.6% vs 36.4%, p = 0.005) without moderate-to-severe PVR in the infolding group. The rate of definitive pacemaker implantation was significantly higher in the infolding group (33% vs 15.7%, p = 0.042). Thus, the overall number of repeated hospitalizations and hospitalizations due to valve procedure-related complications was significantly greater in the infolding group.

Discussion

This multicenter observational study identifies self-expandable prosthesis infolding as a rare intraprocedural complication during TAVI that leads to worse cardiovascular short-term outcomes. The occurrence of infolding is burdened by a higher rate of intraprocedural hemodynamic deterioration, neurologic events, and urgent conversion to aortic surgery; furthermore, mortality and residual mild PVR arise from infolding in the short-term follow-up. The infolding diagnosis could be facilitated by intraprocedural TEE, although fluoroscopic findings are sufficient to make diagnosis. This complication could be overcome by prosthesis recapturing, infolded valve postdilation, valve-in-valve implantation, or bail-out cardiac surgery. Of note, current literature reports that transcatheter prosthesis infolding cases are related only to Medtronic Evolut, suggesting manufacturing and largest size as causal features.

Since the first report of self-expandable prosthesis infolding by Sinning et al in 2012, many authors paid specific attention to this unusual complication.[12] A single-center case series reported an alarming occurrence rate of 3.15%; nevertheless, our multicenter study collected a larger sample identifying an infolding rate of 1.6%.[7] Thus, prosthesis infolding must be considered as a relevant

Table 3
Outcomes at 30-day follow-up

	Observation (n)	Overall (n=1470)	Control (n=1447)	Infolding (n=23)	p-value
All-cause mortality, n (%)	1470	11 (0.7)	10 (0.7)	1 (4.3)	**0.043**
Cardiovascular mortality, n (%)	1470	9 (0.6)	8 (0.6)	1 (4.3)	**0.021**
MACCE, n (%)	1470	24 (1.6)	21 (1.5)	3 (13)	**< 0.001**
Stroke, n (%)	1470				0.730
Mild		23 (1.6)	22 (1.5)	1 (4.3)	
Moderate		7 (0.5)	7 (0.5)	0 (0)	
Severe		1 (0.1)	1 (0.1)	0 (0)	
TIA, n (%)	1470	13 (0.9)	13 (0.9)	0 (0)	0.648
Periprocedural MI, n (%)	1470	4 (0.3)	4 (0.3)	0 (0)	0.801
Bleeding event, n (%)	1470				**< 0.001**
Type 1		223 (15.2)	221 (15.3)	2 (8.7)	
Type 2		90 (6.1)	89 (6.2)	1 (4.3)	
Type 3		18 (1.2)	18 (1.2)	0 (0)	
Type 4		1 (0.1)	0 (0)	1 (4.3)	
Vascular complication, n (%)	1470				0.435
Minor		256 (17.4)	254 (17.6)	2 (8.7)	
Major		76 (5.2)	74 (5.1)	2 (8.7)	
Acute kidney injury, n (%)	1469				0.596
Type 1		122 (8.3)	121 (8.4)	1 (4.3)	
Type 2		7 (0.5)	7 (0.5)	0 (0)	
Type 3		17 (1.2)	16 (1.1)	1 (4.3)	
Type 4		10 (0.7)	10 (0.7)	0 (0)	
PVR, n (%)	1470				**0.005**
Mild		543 (36.9)	527 (36.4)	16 (69.6)	
Moderate-to-severe		23 (1.6)	23 (1.6)	0 (0)	
New onset atrial fibrillation, n (%)	1470	39 (2.7)	39 (2.7)	0 (0)	0.425
Pacemaker implantation, n (%)[a]	1470	206/1295 (15.9)	200/1277 (15.7)	6/18 (33.3)	**0.042**
Repeated hospitalization, n (%)	1057	30 (2.8)	28 (2.7)	2 (10.5)	**0.042**
Repeated hospitalization due to valve procedure-related complication, n (%)	656	13 (2)	11 (1.7)	2 (15.4)	**< 0.001**

Values are n (%).

[a] Percentage are calculated excluding cases with pre-operative pacing device.

MACCE = major adverse cardiac and cerebrovascular events; MI = myocardial infarction; PVR = para-valvular regurgitation; TIA = transient ischemic attack.

valve-related complication given its occurrence rate is comparable to coronary artery obstruction, myocardial injury, left ventricle perforation, or valve malpositioning.[13]

The Medtronic Evolut system was considered in this investigation. Infolding occurred most frequently using the newest Evolut Pro and Evolut Pro+ and twice as much with 34-mm valve size. The Evolut Pro system is characterized by the same frame of Evolut R, with an additional outer skirt at the caudal rows to improve the cover index reducing PVR.[14−16] Preprocedural evaluation of valve loading is pivotal to avoid prosthesis infolding, especially using larger prosthesis, which could overfill the loading capsule. Thus, fluoroscopic examination of the loaded valve can unveil infolding and allow the operator to reprepare the prosthesis for delivery.[6] We suppose that the double skirt confers more stiffness to the nitinol frame, which becomes more prone to deform toward the area of least resistance (inward), especially in case of great calcium valve burden limiting radial expansion.[14] In fact, our evidence showed a significantly smaller calcification volume affecting all the native valve cusps in the control group.

In 2020, a systematic review including 34 cases of Medtronic TAVI infolding highlighted the predisposing factors by prevalence: larger valve, valve oversizing, resheathing, and heavy native valve calcification were identified as the more important items according to empiric real-life experience.[17] Veulemans et al found severe peripheral kinking, right coronary artery cusp calcification, and resheathing maneuvers as independent predictors of infolding; the presence of ≥2 of these factors carried a positive predictive power of 99.5%.[18] Our study corroborated this evidence given resheathing and right coronary artery cusp calcification volume were independent factors of infolding.

Optimal C-arm angulation is pivotal to minimize parallax during all the steps of TAVI. In almost all transfemoral TAVI procedures, the projection to perfectly align aortic annulus and delivery catheter lies in right anterior oblique caudal view; this projection allows definition of the minor axis of the aortic annulus, which is essential for infolding diagnosis during deployment because it could first appear as an underexpansion of the caudal part of the prosthesis.[19] In our study, 1 of 5 infolding cases was diagnosed after complete prosthesis deployment, but only 34.8% of the operators chose a cusp overlap projection in the delivery phase. Besides fluoroscopy, additional imaging monitoring (i.e., TEE) would be useful to diagnose infolding, avoiding bail-out strategies to overcome this complication after full prosthesis release.[20,21] Furthermore, the growing emphasis on infolding has shifted the timing of the diagnosis: in our study, infolding was diagnosed before full release in 78.3% of the cases whereas only 23% of cases were diagnosed before valve implantation in previously published systematic review; thus, postdilation was the preferred treatment method to solve infolding in that review, in contrast to our results showing almost half of the prostheses being recaptured.[17]

Native valve predilation had been considered a useful tool to achieve optimal prosthesis deployment and functioning since the early days of TAVI; however, the predilation rate has decreased over the years owing to operator experience, technologic progress, preprocedural integrated imaging planning, and economic concerns.[22] In our study, we observed a significantly higher rate of predilation in the infolding group, probably related to functional and anatomical criteria of valve dysfunction. In fact, the infolding group showed smaller estimated aortic valve area with greater transvalvular gradient and higher rate of bicuspid anatomy; furthermore, the infolding group was burdened by higher calcium score for both native valve cusps and left ventricle outflow tract, for which predilation is essential to obtain a successful prosthesis expansion. In addition, the incidence of intraprocedural stroke/transient ischemic attack was greater in the infolding group, whereas no significant differences were observed at 30-day follow-up; this is in line with previous evidence that 80% of TAVI-related stroke occurred within the first week and was related to preimplantation smaller valve area, calcification burden, predilation, and new-onset atrial fibrillation.[23] Furthermore, invasive manipulation of the aortic valve is associated to embolization of debris.[24,25] Thus, in our study, the cause of periprocedural neurologic events is debated given it may be related to predilation, repositioning/recapturing maneuver during prosthesis deployment, or postdilation. As expected by the half-moon shape of the infolded prosthesis, we found a significantly higher rate of intraprocedural moderate-to-severe PVR requiring postdilation. This observation could be considered as a cofactor in the smaller survival outcomes of the infolding group given recent studies confirmed the negative impact of post-TAVI PVR.[26,27]

TAVI using self-expandable prosthesis is burdened by a greater need for permanent pacemaker implantation, ranging from 19% to 49%.[28] In our study, 33.3% of infolding cases were associated to permanent pacemaker implantation at 30-day follow-up, in a more than double ratio than that of the control group. This difference was driven by a higher rate of periprocedural high-degree atrio-ventricular block. Despite a slightly greater incidence of baseline right bundle branch block, we assume that permanent pacemaker implantation was related to the greater frequency of predilation and postdilation to overcome heavy calcification and high prosthesis/annulus size ratio, as suggested by previous registries.[22,29,30] The long-term need for pacing dependency in case of infolding must be further investigated.

Transcatheter aortic valve infolding is a rare complication occurring during self-expandable prosthesis deployment that could carry hemodynamic deterioration, urgent conversion to surgery, and intraprocedural neurologic events. Prosthesis infolding must be carefully investigated using fluoroscopy to perform the diagnosis before full release, when recapture is still possible; TEE monitoring could be useful when available. Special attention to infolding must be paid in case of great native valve calcium burden and resheathing maneuvers. Furthermore, even when adequately solved by postdilation or valve-in-valve implantation, infolding is associated to greater mortality and residual paravalvular leakage in the short-term follow-up.

The main limitation of our study is represented by its retrospective design, which does not allow a complete and accurate collection of data for each item; owing to missing data, the regression analysis could be underpowered. The preprocedural imaging planning with multislice computed tomography and cardiac ultrasound was performed using

each center's radiologic protocol without a core laboratory to uniformly assess semiquantitative parameters. Considering the paucity of literature about the topic deriving mostly from reports and case series, our multicenter study could be considered a more structured analysis of real-world data.

Declaration of competing interest

Dr. Agostoni has received consulting fees from: Abbott, AorticLab, Boston Scientific, Cordis, iVascular, Medtronic, Neovasc, Seven Sons, Teleflex, and Terumo. Dr. Veulemans has received consulting fees, travel expenses or study honoraria from Medtronic, Edwards Lifesciences, and Boston Scientific. The remaining authors have no competing interests to declare.

CRediT authorship contribution statement

Andrea Bezzeccheri: Writing – review & editing, Writing – original draft, Visualization, Validation, Supervision, Software, Project administration, Methodology, Formal analysis, Data curation, Conceptualization. **Enrico Poletti:** Conceptualization. **Paul Vermeersch:** Investigation, Conceptualization. **Verena Veulemans:** Investigation, Data curation, Conceptualization. **Jarkko Piuhola:** Investigation. **Seija Kerkelä:** Investigation. **Heidi Lehtola:** Investigation. **Ole De Backer:** Investigation. **Angelo Quagliana:** Investigation. **Concetta Mammone:** Investigation. **Flavio Ribichini:** Investigation. **Edgard Prihadi:** Investigation. **Benjamin Scott:** Investigation. **Carlo Zivelonghi:** Investigation. **Stefan Verheye:** Investigation. **Pierfrancesco Agostoni:** Investigation.

Supplementary materials

Supplementary material associated with this article can be found in the online version at https://doi.org/10.1016/j.amjcard.2024.04.010.

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