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Post-procedural fever after Transcatheter Aortic Valve Implantation (TAVI). A multi-centric study

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SUMMARY

Background: Fever following transcatheter aortic valve implantation (TAVI) poses a clinical challenge, necessitating a comprehensive diagnostic approach to discern between infectious and non-infectious origins. Despite its minimally invasive nature, TAVI disrupts protective anatomical barriers, leading to an increased risk of infection, as well as to aseptic inflammatory responses. Standardized strategies for the management of these patients are lacking.

Methods: We retrospectively analyzed 1074 consecutive patients. Data retrieved from electronic hospital charts included demographics, comorbidities, NYHA functional class, Multidimensional Prognostic Index (MPI), EUROSCORE II and STS risk score, pre- and post-procedural echocardiographic data, and procedural details. Fever was defined as temperature >37.5°C.

Results: Overall, 391 patients (36.4%) experienced at least one episode of fever, in all cases ensuing within the first 2 days after the procedure. Fever lasted only one day (ODF) in most patients (86%). Antibiotic prophylaxis varied, with cefazolin showing the highest efficacy. Management of post-TAVI fever was heterogeneous. Twenty-five percent of febrile patients received an empiric antibiotic therapy, although a presumed site of infection was identified in only 17% of them and just 19 patients (4.9%) had positive blood cultures. Of the 19 patients with positive cultures, 11 had a Gram+ and 8 a Gram- infection. Fever duration, invasive accesses, and clinical suspicion of infection influenced antibiotic initiation. Fever lasting more than one day (MODF) was associated with new-onset atrial fibrillation and prolonged in-hospital stay. Positive blood cultures were linked to higher mortality, especially with Gram- bacteremia. However, patients with short-term fever had a similar mortality to those without fever, highlighting the benign nature of self-limited fever.

Conclusions: Fever is a common complication after TAVI. A watchful waiting strategy is advisable in stable patients without evidence of infection and self-limited episodes of fever, while selected patients may benefit from an aggressive approach.

Keywords: Transcatheter aortic valve implantation (TAVI), fever, antibiotic prophylaxis, infections, Post-TAVI management.

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INTRODUCTION

Fever following transcatheter aortic valve implantation (TAVI) remains a concern in clinical practice. It often triggers an extensive diagnostic work-up, therapeutic interventions that include broad-spectrum antibiotics and prolongs hospitalization [1]. Despite its minimally invasive nature, TAVI disrupts some protective barriers through vascular access, urinary catheterization, and occasional orotracheal intubation. On the other hand, it can cause an aseptic inflammatory response due to the rupture of heavy native valve calcifications, use of contrast media, and re-absorption of eventual hematomas [2]. Therefore, distinguishing between the infectious or non-infectious origin of post-TAVI fever is clinically relevant but may become challenging. A standardized approach to patient evaluation and management has not been coded yet, and this topic has been approached only marginally. Some studies suggest that early febrile episodes, within 72 hours of TAVI, may align more closely with systemic inflammatory response syndrome rather than a bacterial infection [3-5]. Nevertheless, comprehensive data elucidating the prevalence, nature, and outcomes associated with fever post-TAVI remain scarce. The absence of specific guidelines has left individual centers to manage this complication following empiric protocols, based on local expertise.

In light of this gap, our multicenter, observational study aims to investigate the prevalence, underlying causes, and prognostic impact of fever following TAVI. By delineating the spectrum of infective and non-infective triggers and associated outcomes, we hope to provide some elements for tailored management strategies.

METHODS

Patient selection

We retrospectively analysed 1074 consecutive patients admitted to two academic centres (Amiens University Hospital, France and Florence University Hospital, Italy, providing 583 and 491 patients, respectively) between January 2019 and December 2022 for severe aortic stenosis (AS) and approved for TAVI by the local Heart-Team. The study was approved by the institutional ethics committee at each study site in accordance with institutional policies, national requirements, and the tenets of the revised Declaration of Helsinki. Fully anonymized data retrieved from electronic hospital charts included demographics, co-morbidities assessed by Charlson's Comorbidity Index (CCI) [8], NYHA functional class, Multidimensional Prognostic Index (MPI) [9], EUROSCORE II [10] and STS risk score [11], pre- and post-procedural echocardiographic data, and procedural details. All patients were treated with antibiotic prophylaxis on the procedure day. Fever was defined as a temperature >37.5°C as measured with standard forehead thermometers. The timing of fever onset was measured from the day of the procedure. TAVI was performed in a hybrid operating room that was part of cardiac surgery operative block, using a transfemoral, or a transaxillary/transapical approach in selected cases. Following the procedure, patients were admitted to an intermediate care unit, with close multiparametric monitoring for at least 24–48 h, until suitable for discharge. Diagnostic workup of fever and eventual empirical broad-spectrum antibiotic treatment were managed according to the attending physician's judgment.

Long-term follow-up information was systematically drawn from regional health authorities' registers and by telephone interviews. Given the retrospective nature of the study, informed consent was waived, and all patients agreed to participate in the study when contacted for follow-up. The median follow-up duration, calculated from TAVI procedure was 3.3 years (interquartile range [IQR] 3.2-3.4). The primary study objective was to describe the clinical and laboratory characteristics of post-TAVI febrile episodes, their pathogenesis and prognostic impact. We compared three groups of patients: without fever (WF, N=683), with fever lasting only one day (ODF, N=335), and with fever for more than one day (MODF, N=56). To better understand the predictors of non-infective febrile episodes, we excluded from a further analytical step 175 patients who received antibiotics after the procedure for any cause and/or who had a presumable infective cause of fever, and then compared two groups: patients without (WF, N=618) and with (F, N=281) fever. Finally, we repeated the last analysis comparing two propensity score groups matched for sex, age, and hospital centre.

Statistical analysis

Continuous and non-parametric variables were reported as median ± interquartile interval and as

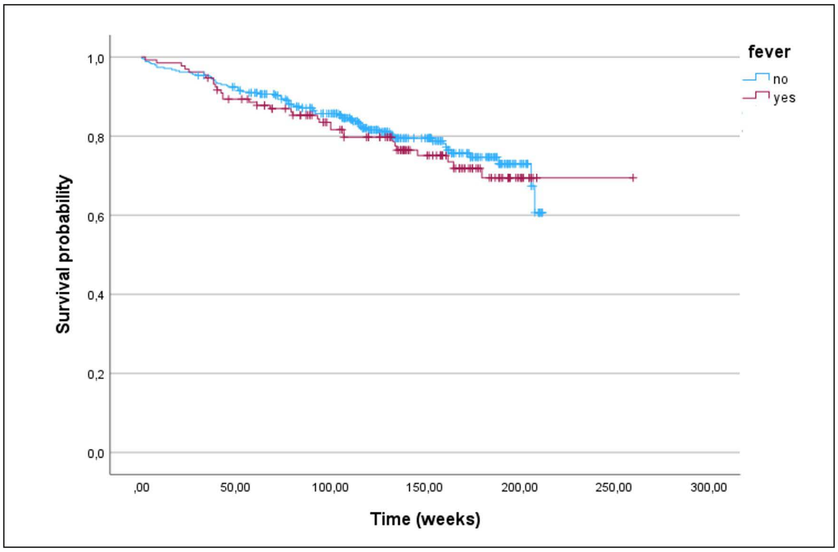

Figure 1
Kaplan Meyer survival analysis of patients with and without fever after TAVI.

numbers and percentages, respectively, and were compared with the Mann-Whitney or chi-square tests. We performed multivariable analyses using logistic regression and adjusting for center. The Kaplan-Meier method was used to estimate the univariable cumulative incidence of survival and Cox-regression analysis to investigate time-dependent variables, such as hospital readmission and endocarditis during the follow-up period. We used the Receiver Operating Characteristic (ROC) analysis to establish the optimal discriminating threshold of continuous variables. All tests were 2-sided, and statistical significance was defined as a p-value <0.05. We performed the analyses with the SPSS 24.0 statistical package R version 3.6.3.

For the propensity score matching analysis, we selected the matching method that provided the best performance in terms of covariate balance among seven matching techniques. In particular, we chose a 1:1 ratio without replacement, without caliper. We checked and compared the performances of the matches in terms of standardized mean differences (SMD) of the covariates also using graphical tools such as love plots and in terms of propensity score distributions before and after the matching. All the variables included in the propensity score model showed a good balance (SMD<0.1). All authors had full access to all the data in the study and took responsibility for its integrity and data analysis.

RESULTS

The clinical characteristics, pre-operative echocardiographic and laboratory data of the 1074 TAVI patients by center are reported in Table 1. Florence patients were older, presented a higher burden of co-morbidities and more severe aortic stenosis. For this reason, multivariable analysis was adjusted for the center.

Overall, in accordance with current indications to TAVI, the median age was 83 years (IQR 83-84), with 50% women [12-13]. The vast majority of patients (92%) had heart failure symptoms (NYHA class >I), and the burden of chronic co-morbidities was rather elevated, as indicated by a median CCI of 6.

Most procedures (96%) were performed on native valves. The SapienTM 3 (Edwards) balloon-expandable prosthesis was the most frequently implanted device (53%), followed by the Evolut self-expandable prosthesis (Medtronic; 36%). The average procedure duration was 88±45 minutes. Permanent pacemaker (PM) implantation (N=158, 14.7%), new-onset paroxysmal atrial fibrillation (N=96, 8.9%), and peri-procedural stroke (N=40, 3.8%), were the most common in-hospital complications. In-hospital mortality was 5.4%.

Antibiotic prophylaxis consisted of Cefazolin in 51.3% of patients, Vancomycin in 33.5%, Amoxicillin/clavulanate in 7.3% and other antibiotics in 7.9%. Cefazolin was associated with the lowest

Table 1 - Demographic, echocardiographic and periprocedural characteristics of 1074 patients with severe aortic stenosis treated with transaortic valve implantation.

	Whole cohort	*Amiens (N=583)*	*Florence (N=491)*	*p-value*
Female sex, N (%)	539 (50.2%)	251 (43.1%)	288 (58.7%)	<0.001
Age, years, Median [IQR]	83 [83-84]	81 [81-82]	84 [84-85]	<0.001
BMI, Median [IQR]	26.0 [25.8-26.5]	27 [26-27]	25 [24-25]	<0.001
Hypertension, N (%)	916 (85.3%)	496 (85.2%)	419 (85.3%)	0.96
NYHA class, N (%)				
I	83 (8.1%)	(11%)	(4.5%)	P<0.001
II	360 (35.2%)	(38.6%)	(30.7%)	
III	495 (46.4%)	(41.2%)	(57.7%)	
IV	85 (8.3%)	(9.2%)	(7.1%)	
EUROSCORE II log, Median [IQR]	2.49 [2.37-2.67]	2 [1.9-2.1]	4 [3.8-4.3]	<0.001
Charlson Index, Median [IQR]	6 [6-7]	5 [5-6]	7 [7-8]	<0.001
IVS, Median [IQR]	13 [13-14]	13 [13-14]	13 [13-14]	<0.001
EF, Median [IQR]	59 [58-60]	60 [60-63]	55 [55-58]	<0.001
AVA, cm^2, Median [IQR]	0.78 [0.76-0.8]	0.8 [0.8-0.83]	0.7 [0.7-0.8]	0.3
Gmed, mmHg, Median [IQR]	74 [72-76]	45 [45-47]	46 [45-48]	0.82
DVI, Median [IQR]	0.21 [0.21-0.22]	0.21 [0.21-0.22]	0.20 [0.20-0.22]	0.24
Duration of intervention, minutes, Median [IQR]	81 [80-85]	78 [76-81]	87 [85-91]	<0.001
Valve-in-valve, N (%)	41 (3.8%)	2 (0.3%)	39 (7.9%)	< 0.001
New-onset AF, N (%)	96 (8.9%)	54 (9.3%)	42 (8.6%)	0.68
PM implantation, N (%)	158 (14.7%)	110 (18.9%)	48 (9.8%)	<0.001
Post-procedural stroke, N (%)	40 (3.8%)	25 (4.2%)	15 (3%)	0.28
SAPT, N (%)	360 (33.5%)	256 (44%)	104 (21.2%)	<0.001
DAPT, N (%)	383 (35.7%)	137 (23.5%)	245 (50%)	<0.001
OAC therapy, N (%)	393 (36.6%)	215 (36.8%)	178 (36.2%)	0.9
Fever, N (%)	391 (36.4%)	254 (43.6%)	137 (27.9%)	<0.001

AF: atrial fibrillation. AVA: aortic valvular area. BMI: body mass index. DAPT: dual anti platelet therapy. DVI: Doppler Velocity Index. EF: ejection fraction. G med: medium gradient. IVS: interventricular septum. OAC: oral anti-coagulant. PM: pacemaker. SAPT: single antiplatelet therapy.

use of post-procedural antibiotics (5.8% vs 22%, 23% and 34%, respectively, p <0.001).

Overall, 391 patients (36.4%) experienced at least one episode of fever, in all cases ensuing within the first 2 days after the procedure. Fever lasted only one day (ODF) in most patients (86%).

The management of fever was variable. Blood and/or urine cultures were performed in 22% of patients with fever; 24 patients had positive blood cultures and 40 patients had positive urine cultures. Twenty-five percent of febrile patients received an empiric antibiotic therapy, although a presumed site of infection was identified in only 17% of them and just 19 patients (4.9%) had positive blood cultures. Of the 19 patients with positive cultures, 11 had a Gram+ and 8 a Gram- infection. An empirical antibiotic therapy was started more frequently in patients with fever lasting more than 1 day (MODF, p<0.001), in patients with a central venous access or a urinary catheter for >48 hours (p<0.001), and in those with a presumable site of infection (p<0.001). Positive blood cultures were significantly more frequent in patients with pre- and post-procedural higher levels of C-

Reactive Protein (CRP) and procalcitonin. The best predictive value for a positive blood culture was 182 mg/dl for post-procedural CRP (AUC=0.74) and 1.27 ng/ml for post-procedural procalcitonin (AOU=0.81).
As shown in Table 2, comparing the 3 groups, valve-in-valve procedure was less frequently associated with fever than procedures on native valves (p=0.007). Fever, especially if lasting more than one day, was significantly associated with the persistence for more than 48 hours of a central venous catheter, a delivery sheath or a urinary catheter, while was inversely correlated with early mobilization (all p<0.001). In patients with MODF, blood or urine cultures were more often positive, a presumable site of infection was more frequently found, and the need for post-procedural antibiotics was more common. Laboratory analysis showed a significantly higher post-procedural CRP in patients with more prolonged fever, although a significant increase in CRP was seen also in patients with ODF compared with those without fever (86 mg/l vs. 25 mg/l vs. 19 mg/l respectively; p <0.001). In patients with MODF, we observed a higher incidence of new-onset atrial fibrillation (p=0.018), a more frequent need for PM implantation (p=0.002) and a longer in-hospital stay (p<0.001). At multivariable analysis, the association with PM implantation was not independent, probably being a consequence of the late sheath removal.
When comparing patients with one-day-long fever (ODF) to those with fever lasting more than one day (MODF) after TAVI, several notable differences emerge. The MODF group experienced a higher prevalence of prolonged central venous catheterization (19.6% vs. 6.3%) and urinary catheterization (55.4% vs. 29.6%), indicating greater exposure to invasive procedures. Immediate sheath removal was less frequent in MODF patients (21.4% vs. 28.7%), and early mobilization within 48 hours was significantly less common (44.6% vs. 77.6%). Infections were markedly more frequent in the MODF group, with higher rates of positive blood cultures (7.1% vs. 4.5%), positive urine cultures (14.3% vs. 5.7%), and identified sites of infection (46.4% vs. 11.6%). These patients also required antibiotics more often (64.3% vs. 18.8%) and had elevated inflammatory markers, as evidenced by a higher median peak CRP (86 mg/dL vs. 25 mg/dL). Furthermore, new-onset atrial fibrillation (19.6% vs. 8.4%) and pacemaker implantation (30.4% vs. 15.5%) were more frequent in the MODF group. Hospital stays were also notably longer for MODF patients, with a median of 10 days compared to 6 days in the ODF group. These

Table 2 - Significantly different covariates among patients treated with TAVI without post-procedural fever (WF, N=683), with one-day-long fever (ODF, N=335) and with fever lasting more than one day (MODF, N=56).

	WF (N=683)	*ODF (N=335)*	*MODF (N=56)*	*p value*
Valve-in-valve, N (%)	36 (5.3%)	4 (1,2%)	1 (1.8%)	0.007
CVC >48 h, N (%)	35 (5.1%)	21 (6.3%)	11 (19.6%)	<0.001
UC >48 h, N (%)	241 (35.3%)	99 (29.6%)	31 (55.4%)	<0.001
Immediate sheath removal, N (%)	271 (39.7%)	96 (28.7%)	12 (21.4%)	<0.001
Mobilization within 48 h, N (%)	503 (73.6%)	260 (77.6%)	25 (44.6%)	<0.001
Positive blood culture, N (%)	5 (0.7%)	15 (4.5%)	4 (7.1%)	<0.001
Positive urine culture, N (%)	13 (1.9%)	19 (5.7%)	8 (14.3%)	<0.001
Site of infection, N (%)	42 (6.1%)	39 (11.6%)	26 (46.4%)	<0.001
Antibiotics after TAVI, N (%)	60 (8.8%)	63 (18.8%)	36 (64.3%)	<0.001
Peak CRP, mg/dl, median [IQR]	19 [16-22]	25 [51-93]	86 [60-102]	<0.001
New-onset AF, N (%)	57 (8.3%)	28 (8.4%)	11 (19.6%)	0.018
PM implantation, N (%)	89 (13%)	52 (15.5%)	17 (30.4%)	0.002
LoS, days, median [IQR]	6 [6-7]	6 [6-7]	10 [8-13]	<0.001

CCI: Charlson comorbidity index. CRP: C Reactive Protein. CVC: central venous catheter. UC: urinary catheter. LoS: length of stay in hospital.

findings highlight that prolonged fever is associated with increased procedural complications, infections, and recovery challenges.

Multivariable analysis of a-priori predictors of fever (immediate sheath removal, valve-in-valve procedure, central venous catheters > 48 hours, mobilization within 48 hours, post-procedural CRP peak) was adjusted for the center and is shown in Table 3. We included in the multivariable analysis all the significant covariates of Table 2 that were not a consequence of fever (i.e. prolonged hospital stay) or already a diagnosis of infection (i.e. positive cultures).

When we compared WF and F groups with exclusion of patients who received post-procedural antibiotic therapy and/or with a presumable site of infection, we found that fever was more frequent in patients undergoing procedures on native valves (32.3 vs 3.1%, p <0.001), and in those with prolonged maintenance of femoral sheath (36.4 vs 22.9%, p<0.001), thicker interventricular septum (13.4±2.5 vs 12.8 ± 2.5 mm, p=0.005), higher mean transaortic gradient (49.11±14.2 vs 46.8±16.3 mmHg, p=0.012), or lower Doppler Velocity Index (0.19±0.04 vs 0.22±0.07, p<0.001). After propensity score matching analysis, fever was associated with native-valve procedures (p=0.009) and Aortic Valve Area (AVA, cm^2, p=0.04; data not shown).

Overall, post-procedural fever prolonged in-hospital stay when lasting more than one day (p<0.001) but was not associated with increased mortality (Figure 1), nor with the onset of infective endocarditis during the follow-up. However, the subset of patients with positive blood cultures had a significantly higher mortality (p=0.044), especially those with Gram- cultures (HR 2.9, CI95% 1.06-8.07). Of note, 5 WF patients had positive blood cultures (4 for Gram+ and 1 for Gram- bacteria), and 2 of them died in-hospital.

DISCUSSION

Table 3 - Independent predictors of fever at multivariable analysis.

	*HR**	*95%CI*	*p value*
CVC >48 h	2	1.0-4.1	0.046
Peak CRP	1.01	1.007-1.014	<0.001

CRP: C Reactive Protein. CVC: central venous catheter.
*HR per unit for continuous variables.

Our retrospective study sheds light on the clinical course and outcomes of post-procedural fever following TAVI in a sizable cohort of patients across two academic centers.

The incidence of fever post-TAVI, occurring in 36.4% of cases, highlights the relevance of this phenomenon in the clinical practice. Most febrile episodes manifested within the initial 48 hours after the procedure, with a majority resolving within a day, aligning with previous reports regarding the timing of post-TAVI fever onset [1-4]. This observation corroborates existing literature, suggesting that early vigilance for fever is paramount in the post-procedural period [5].

At least 72% of patients with fever presented a presumable generic inflammatory reaction in the absence of a definite infection, as reported previously [5]. The management of post-TAVI fever remains heterogeneous, reflecting the absence of standardized guidelines. Despite a low rate of positive blood cultures (4.9%), empirical antibiotic therapy was administered to a quarter of febrile patients, suggesting a tendency toward overtreatment. Notably, the decision to initiate antibiotics was influenced by the duration of fever, the presence of a central venous or urinary catheter, and clinical suspicion of infection. The association between elevated inflammatory markers and positive blood cultures suggest the potential utility of these markers in guiding antibiotic therapy decisions.

The etiology of post-TAVI fever is multifactorial, encompassing both infectious and non-infectious mechanisms. The occurrence of fever, particularly if lasting more than one day, was probably the consequence of in-hospital infections or presumable transient bacteremia, and was associated with further complications, as new-onset atrial fibrillation and prolonged hospital stay. Conversely, in patients with short-course fever and without signs of infection, the correlation with native valve procedures and smaller valve areas may support the hypothesis of an inflammatory reaction secondary to the impingement of the device into cardiac tissues [5]. An inflammatory response has been observed following other cardiovascular procedures, such as percutaneous coronary intervention or cardiac surgery [3]. A systemic inflammatory reaction syndrome is also common after endovascular graft deployment for the correction of aortic aneurysms, a procedure sharing similarities with TAVI.

However, we also found an association with potential bacterial entry sites, as venous accesses, which highlights the importance of a watchful post-procedural strategy and a "minimalistic" procedural approach (local anesthesia; no urinary catheter; pacing via the left ventricular wire; radial as secondary arterial line immediately removed post-procedure; mobilization within 4-6 hours post-TAVI).

Our study did not find an association between post-TAVI fever and increased mortality or the development of infective endocarditis during follow-up. However, patients with positive blood cultures exhibited a significantly higher mortality rate, particularly in the presence of Gram- bacteremia, underscoring the importance of early recognition and targeted management of post-TAVI infective complications. Moreover, antibiotic prophylaxis is targeted on Gram+ bacteria, while prevention of Gram- infections mostly relays on sterility of access and early urinary catheters removal.

Of note, two out of five patients with positive blood cultures in the absence of fever, died; this observation confirms the need of a high level of suspicion for infection in this subset of frail patients, who may develop insidious clinical pictures without overt signs of infection.

In previous reports, both sepsis and systemic inflammatory reaction syndrome have been associated with worse outcomes following TAVI [3-4]. However, the prevalence of fever was evaluated mostly in the early years of TAVI, when most procedures were performed under general anesthesia, with prolonged stay in intensive care. In the last years, the minimalistic approach including use of conscious sedation has dramatically changed post-TAVI morbidity, so that we can conclude that patients with short-term self-limited febrile episodes have the same mortality rate as patients without fever, while septic complications increase significantly post-procedural mortality.

The etiology of post-TAVI fever is multifactorial, encompassing both infectious and non-infectious mechanisms. On the basis of our observations, we cannot a priori distinguish between an inflammatory reaction and an even transient bacteremia, but we add elements to identify high-risk patients, for whom an aggressive approach is advisable, and low-risk ones, for whom a watchful-waiting strategy is reasonable. Based on our results, post-TAVI fever is – though quite common – a substantially benign event and, therefore, a watchful waiting strategy is reasonable in stable patients, especially without overt signs of infection and with lower levels of CRP. If an infectious source is not identified, immediate empirical antibiotic treatment is not mandatory, unless high-risk predictors are present (high levels of CRP; procalcitonin; long-standing invasive accesses; fever lasting more than one day). This approach may reduce the use of broad-spectrum antibiotics, with important implications for germ resistance.

Our study is limited by its retrospective nature. The absence of a standardized approach to post-TAVI fever management underscores the need for further, prospective research with standardized management, to delineate optimal diagnostic and therapeutic protocols in this population. Prospective studies including multimodal assessments, clinical, laboratory, and imaging parameters, are warranted to refine risk stratification and guide tailored management. Additionally, efforts to develop consensus guidelines for the evaluation and management of post-TAVI fever are imperative to mitigate variability in clinical practice and optimize patient outcomes in this frail population.

CONCLUSIONS

Our study highlights the importance of discerning between infectious and non-infectious causes of post-TAVI fever, in order to optimize patient management strategies. Fever after TAVI is common and is often a self-limited phenomenon. Withholding antibiotics in an otherwise stable, low-risk TAVI patient with a brief and isolated temperature increase, could be reasonable. However, prolonged high-grade fever or fever in high-risk patients, warrant further investigation and prompt treatment.

Conflict of interest
None to declare

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Authors contribution
All authors take responsibility for all aspects of the reliability and freedom from bias of the data presented and their discussed interpretation.

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