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***Original Article** / Özgün Makale*

Clinical outcomes after transcatheter aortic valve implantation in active cancer patients and cancer survivors

Aktif kanseri olan ve kanser sonrası sağ kalanlarda transkateter aort kapak implantasyonunu takiben klinik sonuçlar

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ABSTRACT

Background: In this study, we aimed to evaluate the clinical characteristics, perioperative, and mid-term outcomes of patients with severe symptomatic aortic stenosis and active cancer disease and cancer survivors undergoing transcatheter aortic valve implantation.

Methods: Between December 2011 and March 2019, a total of 550 patients (248 males, 302 females; mean age: 77.6±7.9 years; range, 46 to 103 years) who underwent transcatheter aortic valve implantation for severe symptomatic aortic stenosis in our center were retrospectively analyzed. Baseline demographic characteristics, cancer type, laboratory data, procedural data, and outcome data of the patients were collected. The primary outcome measure was all-cause mortality at 30 days and every six months up to maximally available follow-up. Follow-up was performed at 30 days, six months, and 12 months after the procedure and annually thereafter.

Results: Of the patients, 36 had a cancer diagnosis-active (n=10) or cured (n=26). The most common types of cancer were colorectal (16.6%), prostate (13.8%), leukemia (11.1%), and bladder (11.1%) cancers. Post-procedural complication rates were similar between the two groups. No mortality was observed in the cancer group at one month of follow-up. During follow-up, seven patients died within one year due to non-cardiac reasons. Although mortality at one year was higher in cancer patients, it did not reach statistical significance (23.3% vs. 11.6%, respectively; p=0.061). The estimated cumulative survival rate was 71.0% in the non-cancer group and 58.3% in the cancer group. The multivariate Cox regression analysis revealed that cancer was independently associated with cumulative mortality after adjusting for age, sex, body mass index, and atrial fibrillation (p=0.008).

Conclusion: Our study results show that transcatheter aortic valve implantation is safe and feasible in active cancer patients and cancer survivors with similar short-term and mid-term mortality and procedure-related complication rates, compared to non-cancer patients.

Keywords: Aortic stenosis, cancer, cancer survivors, transcatheter aortic valve implantation.

ÖZ

Amaç: Bu çalışmada, transkateter aort kapak implantasyonu yapılan aktif kanser veya kanser sonrası sağ kalan şiddetli semptomatik aort darlığı olan hastaların klinik özellikleri, ameliyat sırası ve orta dönem sonuçları değerlendirildi.

Çalışma planı: Aralık 2011 - Mart 2019 tarihleri arasında merkezimizde şiddetli semptomatik aort darlığı nedeniyle transkateter aort kapak implantasyonu yapılan toplam 550 hasta (248 erkek, 302 kadın; ort. yaş: 77.6±7.9 yıl; dağılım, 46 to 103 yıl) retrospektif olarak incelendi. Hastaların başlangıç demografik özellikleri, kanser türü, laboratuvar verileri, işlem ve sonuç verileri toplandı. Primer sonuç ölçümü, 30. günde ve maksimum takip süresine kadar her altı ayda bir tüm nedenlere bağlı mortalite idi. Takipler işlem sonrası 30. gün, altıncı ay ve 12. aylarda ve sonrasında yıllık olarak yapıldı.

Bulgular: Hastaların 36'sında (%6.5) aktif (n=10) ya da kür sağlanmış kanser (n=26) tanısı mevcuttu. En sık görülen kanserler kolorektal (%16.6), prostat (%13.8), lösemi (%11.1) ve mesane (%11.1) kanserleri idi. İşlem sonrası komplikasyon oranları iki grup arasında benzerdi. Bir aylık takipte kanser grubunda ölüm görülmedi. Takip sırasında bir yıl içinde kardiyak dışı nedenlere bağlı yedi hasta kaybedildi. Birinci yılda ölüm oranının kanser hastalarında daha yüksek olmasına rağmen, istatistiksel anlamlılığa ulaşmadı (sırasıyla, %23.3'e kıyasla %11.6; p=0.061). Tahmini kümülatif sağkalım oranı, kanser olmayan grupta %71.0 ve kanser grubunda %58.3 idi. Çok değişkenli Cox regresyon analizinde, yaş, cinsiyet, vücut kütle indeksi ve atriyal fibrilasyona göre ayarlama yapıldıktan sonra, kanserin kümülatif mortalite ile bağımsız olarak ilişkili olduğu görüldü (p=0.008).

Sonuç: Çalışma sonuçlarımız, kanser olmayan hastalara kıyasla, aktif kanser hastaları ve kanser sonrası sağ kalanlarda transkateter aort kapak implantasyonunun benzer kısa dönem ve uzun dönem mortalite ve işleme bağlı komplikasyon oranları ile güvenli ve uygulanabilir olduğunu göstermektedir.

Anahtar sözcükler: Aort darlığı, kanser, kanser sonrası sağ kalanlar, transkateter aort kapak implantasyonu.

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Transcatheter aortic valve implantation (TAVI) is an option for treatment of patients with severe symptomatic aortic stenosis (AS) who are at an intermediate or high risk for surgical aortic valve replacement (SAVR).[1] Current recommendations by the European Society of Cardiology (ESC) Guidelines on the Management of Valvular Heart Disease[1] state that TAVI should be carried out in patients with a life expectancy of >one year, as the benefit of TAVI may be reduced in patients with low life expectancy due to non-cardiac causes.[1] Therefore, patients with a life expectancy of <2 years due to malignancy were not included in large, randomized TAVI trials.[2-5] Advances in cancer treatment have led to improved survival; therefore, the number of cancer survivors continues to increase rapidly, as the population ages. Yusuf et al.[6] showed that patients with cancer with non-treated severe AS had worse outcomes compared to those treated with SAVR. Compared to SAVR, TAVI is less invasive and has a shorter hospitalization duration, which provides a faster recovery and more rapid restoration of activities of daily living.

In the present study, we aimed to evaluate the clinical characteristics, perioperative, and mid-term outcomes of patients with severe symptomatic AS and active cancer disease and cancer survivors undergoing TAVI.

PATIENTS AND METHODS

This single-center, retrospective study was conducted at Ankara Atatürk Training and Research Hospital between December 2011 and March 2019. A total of 550 patients (248 males, 302 females; mean age: 77.6±7.9 years; range, 46 to 103 years) who underwent TAVI for severe symptomatic AS were included in the study. Of 550 patients, 36 had a cancer diagnosis. The patients were divided into two groups as those with active cancer (n=10) and those without cancer (n=26). Baseline characteristics, cancer type, and time of diagnosis, cancer stage, the state of cancer (cure or active), laboratory data, procedural data, and outcome data were recorded. Post-procedural follow-up was performed at 30 days, six months, and 12 months. The cut-off date for survival data was December 2019. The primary outcome measures included pre-procedural, 30-day, six-month, 12 month, and final follow-up all-cause mortality and cause of death, changes in the New York Heart Association (NYHA) functional class, transcatheter valve gradients and presence of paravalvular leakage, vascular complications, peri-procedural bleeding, and stroke. A written informed consent was obtained from each patient. The study protocol was approved by the Ankara Atatürk Training and Research Hospital Ethics Committee (Date, No: March 2011-068). The study was conducted in accordance with the principles of the Declaration of Helsinki.

Pre-procedural evaluation

The Heart Team selected all patients based on a clinical consensus. The devices were delivered through the transfemoral and transaxillary approach. The procedural details are presented in the previous study.[7]

The patients with cancer were classified as active cancer patients (non-cured) and cancer survivors (cured) patients. The diagnosis was confirmed by a specialist (i.e., oncologist, hematologist, or urologist) in all patients, and the patients only received TAVI, if the life expectancy was estimated as longer than one year. Among the cured group, survival was defined as disease-free survival for at least five years without any evidence of relapse.

Statistical analysis

Statistical analysis was performed using the IBM SPSS version 22.0 (IBM Corp., Armonk, NY, USA). Continuous variables were presented in mean ± standard deviation (SD) or median (min-max) and compared using t-tests for data complying with a normal distribution or Mann-Whitney U test for data complying with non-normal distribution. Categorical variables were presented in number and frequency and compared using the chi-square test. The Kaplan-Meier method and the log-rank test were performed to estimate the cumulative incidences of mortality. A multivariable Cox proportional hazard survival model with covariate adjustments was used to prespecify covariates in the multivariate model and age, sex, body mass index (BMI), and preoperative atrial fibrillation (AF) were included. A two-tailed p value of <0.05 was considered statistically significant.

RESULTS

Thirty-six (6.5%) patients had a diagnosis of cancer. Of these patients, 10 had active cancer with no metastases, while 26 patients were cancer survivors. The rate of AF was significantly higher in the non-cancer group (p=0.023). Baseline echocardiographic and laboratory parameters were also similar between the two groups. The demographic and clinical features of the patients are shown in Table 1.

The access site, type of valve, and valve size did not significantly differ between the two groups (Table 1).

Table 1. Baseline demographic and clinical features of patients

	Cancer (n=36)		No cancer (n=514)		
	%	Mean±SD	%	Mean±SD	*p*
Age (year)		74.6±6.5		77.8±8.0	0.021
Female (%)	69.4		57.0		0.002
Body mass index (kg/m²)		25.0±3.9		27.9±6.2	0.043
New York Heart Association functional class (%)					0.237
II	36.1		25.5		
III	47.2		56.9		
IV	11.1		15.5		
Pulmonary edema	5.5		2.0		
Diabetes mellitus (%)	19.4		30.2		0.172
Hypertension (%)	75.0		82.6		0.247
Atrial fibrillation (%)	8.3		25.1		0.023
Stroke (%)	2.8		5.5		0.481
Society of Thoracic Surgeons score		4.8±3.2		6.1±3.5	0.115
EuroSCORE II		7.4±4.9		9.1±5.8	0.289
Coronary artery disease					0.459
Normal	27.7		32.4		
Non-obstructive	52.7		42.2		
Obstructive	19.4		25.3		
Previous CABG (%)	19.4		23.6		0.563
Moderate to severe COPD (%)	38.8		42.4		0.843
Pre-antiplatelet/anticoagulation (%)					0.046
ASA or P2Y12 alone	91.7		71.4		
ASA + P2Y12	5.6		3.5		
Warfarin alone	2.8		22.5		
ASA + warfarin	-		-		
ASA + warfarin + clopidogrel	-		-		
Warfarin + clopidogrel	-		-		
DOAC alone	-		2.5		
DOAC + clopidogrel	-		-		
DOAC + ASA + clopidogrel	-		-		
Post-antiplatelet/anticoagulation (%)					0.932
ASA or P2Y12 alone	8.4		3.0		
ASA + P2Y12	75.0		67.4		
Warfarin alone	5.6		7.0		
ASA + warfarin	2.8		4.9		
ASA + warfarin + clopidogrel	-		5.8		
Warfarin + clopidogrel	6.9		6.0		
DOAC alone	2.8		4.5		
DOAC + clopidogrel	-		2.0		
DOAC + ASA + clopidogrel	-		0.4		
Echocardiographic and laboratory parameters					
LVEF (%)		55.6±11.2		51.6±13.9	0.092
Aortic max gradient (mmHg)		79.6±18.8		82.0±23.9	0.585
Aortic mean gradient (mmHg)		49.3±11.7		50.8±15.4	0.580
AVA (cm²)		0.70±0.15		0.67±0.16	0.272
sPAP (mmHg)		42.0±16.9		43.8±16.9	0.545
Serum glucose		111.8±32.1		128.9±56.2	0.073
Creatinine (mg/dL)		1.4±0.9		1.1±0.7	0.062
Hemoglobin (mg/dL)		11.3±1.8		11.7±1.9	0.246
Platelets (10^9/L)		233.7±62.1		241.4±85.2	0.597
Procedural characteristics					
Access site (%)					
Transaxillary	5.5		3.5		0.770
Transfemoral	94.5		96.5		0.685
Cut-down	5.5		5.7		0.871
Edwards SAPIEN XT (%)	86.1		86.8		0.897
Edwards SAPIEN 3 (%)	11.1		8.5		0.558
Lotus (%)	2.7		4.6		0.558
Prosthesis size ≥29 mm (%)	19.4		12.9		0.596

SD: Standard deviation; CABG: Coronary artery bypass grafting; COPD: Chronic obstructive pulmonary disease; AVA: Aortic valve area; DOAC: Direct oral anticoagulant; LVEF: left ventricular ejection fraction; sPAP: Systolic pulmonary artery pressure.

Table 2. Cancer types

	n
Colorectal	6
Prostate	5
Chronic lymphocytic leukemia	4
Bladder	4
Lung	3
Breast	3
Lymphoma	3
Myelodysplastic syndrome	2
Stomach	2
Laryngeal	1
Bone	1
Lymphoma + prostate	1
Malign mesenchymal tumor	1
Total	36

The transfemoral approach was used to the majority of both cancer and non-cancer groups. The peri-procedural complication rates (i.e., permanent pacemaker, major vascular complication, stroke, major bleeding, myocardial infarction) were similar between the two groups. The mean discharge period after TAVI was 4.9±2.5 days, and there was no statistically significant difference between the groups (p=0.375). There was no in-hospital mortality or stroke in any of the patients.

The primary treatment strategy was to use dual antiplatelet therapy for six months after TAVI. However, in the patients who needed oral anticoagulation and underwent percutaneous coronary intervention, treatment was applied considering the risk factors of the bleeding status and thrombosis. The study population was heterogeneous in terms of diseases including coronary artery disease, percutaneous coronary intervention, AF, and mechanical valve prosthesis. The use of antiplatelets and anticoagulants before and after TAVI is given in Table 1.

Table 2 shows the types of cancer. The most common cancers were colorectal (16.6%), prostate (13.8%), leukemia (11.1%), and bladder (11.1%) cancers. At the time of TAVI, 11.1% of the patients had advanced cancer (Class III to IV), while 72% were cured. Five cancer patients had radiotherapy, and three of those patients received radiotherapy to the mediastinum. Fifteen of cancer patients had chemotherapy. Cancer surgery was performed for eight patients following TAVI.

Intra-procedural, in-hospital outcomes, 30-day mortality, and one-year mortality rates are provided in Table 3. The 30-day and one-year survival status were available in 97.2% and 80.5% of patients, respectively. No mortality was observed in the cancer group during one-month follow-up. At follow-up, seven patients died within one year due to non-cardiac reasons. Although mortality at one year was only numerically higher in cancer patients, it did not reach statistical significance (23.3% vs. 11.6%, respectively; p=0.061). The Kaplan-Meier estimates of survival are shown in Figure 1. The estimated cumulative survival was 71% in the non-cancer group and 58.3% in the cancer group. The Multivariate Cox regression analysis revealed that

Table 3. Procedural outcomes and mortality

	Cancer (n=36)		No cancer (n=514)		
	%	Mean±SD	%	Mean±SD	*p*
Pacemaker (%)	2.7		7.9		0.506
Major vascular complication (%)	5.5		7.1		0.393
Discharge time (day)		4.9±2.5		4.5±2.3	0.375
Stroke (%)	2.7		5.5		0.481
Intra-procedural myocardial infarction (%)	0		0		-
Major bleeding (%)	5.5		3.2		0.295
In-hospital mortality (%)	0.0		4.2		0.205
30-Day mortality (%)	0.0		3.4		0.266
First-year mortality (%)	23.3		11.6		0.061
Total mortality (%)	41.7		29.0		0.108
Mean follow-up time (month)		14.6±10.3		15.8±15.3	0.636

SD: Standard deviation.

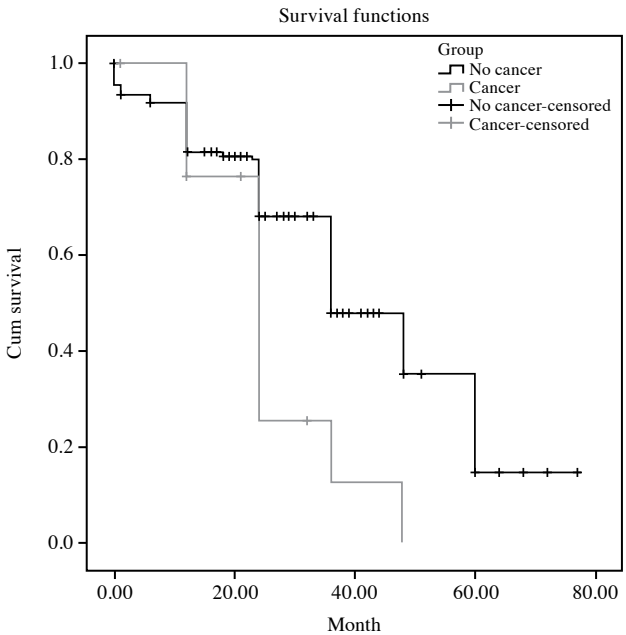

Figure 1. Kaplan-Meier unadjusted analysis of survival curves in patients with and without cancer. Overall survival probability was significantly different in those patients with cancer or without cancer (overall group; mean: 40.2±1.7 95% CI: 36.8-43.5, Non-cancer group; mean: 41.5±1.7 95% CI: 38.0-45.0, cancer group mean: 25.8±2.8 month 95% CI: 20.1±31.4, log-rank p=0.030).

CI: Confidence interval.

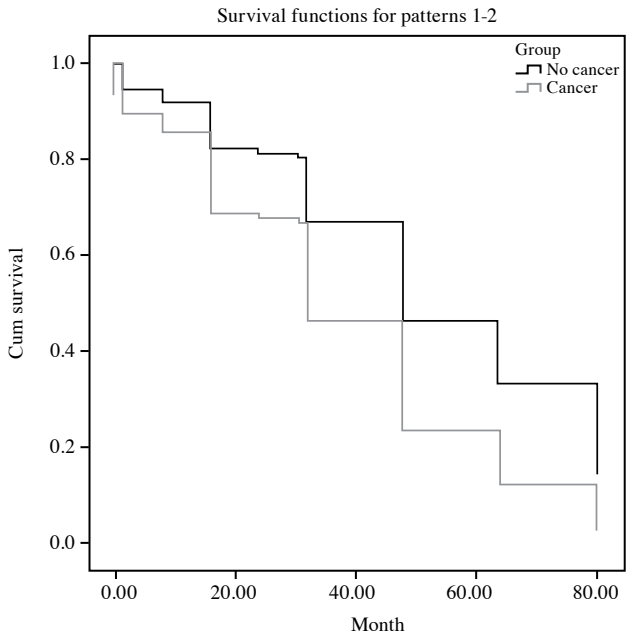

Figure 2. Cox-adjusted with age, sex, body mass index, and atrial fibrillation history analysis of survival curves in patients with cancer or without cancer groups. The presence of cancer was independently associated with cumulative mortality (HR: 1.67, 95% CI: 1.15-2.40, p=0.008).

HR: Hazard ratio; CI: Confidence interval.

cancer was independently associated with cumulative mortality after adjusting for age, sex, BMI, and AF. The presence of cancer was independently associated with cumulative mortality (hazard ratio [HR]: 1.67, 95% confidence interval [CI]: 1.15-2.40, p=0.008) (Figure 2). All patients in both groups showed a statistically significant recovery in the functional capacity.

The mean post-procedural gradient of the bioprosthetic aortic valve was 10.7±4.1 mmHg, and a significant decrease was observed in all groups. There was no significant change in the mean gradient in both groups at 30-day follow-up (Table 4). There was no moderate or severe paravalvular aortic leak in any patient, both after the procedure and at one month.

DISCUSSION

In this study, we evaluated the frequency, clinical characteristics, perioperative and mid-term outcomes, and mortality of cancer patients undergoing TAVI. The main findings are as follows: *(i)* Cured and active cancer disease were present in 6.5% of the patients; *(ii)* The most common types of cancers were prostate, leukemia, and bladder cancers; and *(iii)* The TAVI

Table 4. Follow-up echocardiographic parameters

	Cancer (n=36)	No cancer (n=514)	
	Mean±SD	Mean±SD	*p*
Post-TAVI LVEF (%)	58.7±8.9	53.8±12.8	0.031
Post-TAVI aortic mean gradient (mmHg)	10.7±4.1	10.5±4.9	0.799
30-Day LVEF (%)	58.4±8.9	55.1±11.4	0.190
30-Day aortic mean gradient (mmHg)	10.7±4.1	10.5±4.9	0.089

SD: Standard deviation; TAVI: Transcatheter aortic valve implantation; LVEF: Left ventricular ejection fraction.

procedure was safe and feasible in the cancer patients with similar short-term and mid-term mortality and peri-procedural complication rates, compared to non-cancer patients; *(iv)* Post-procedural and 30-day valve performance did not significantly differ between the two groups.

Although the benefit of valve replacement was demonstrated in patients with severe symptomatic AS, an extensive registry found that one-third of the patients did not undergo surgery.[8] One of the most important reasons for declining surgery is cancer.[9] Nevertheless, in a retrospective study, cancer patients undergoing SAVR were shown to have better mortality outcomes, compared to medical treatment.[6] However, possible complications such as bleeding and infection that may be seen in cancer patients undergoing SAVR should be kept in mind. The less invasive TAVI procedure performed by the transfemoral access seems to be a better option for all cancer patients, particularly hematological cancers, where the risk of bleeding complications is high. As expected, in our study, TAVI was performed with the same complication rates and device success in cancer and non-cancer group.

The data on TAVI in cancer patients are uncommon. In our study, active cancer and cured cancer were present in 6.5% of the patients. In the study by Tabata et al.,[10] which included 1,568 TAVI patients, 19% had an active or previous cancer history. In another study, Biancari et al.,[11] in the Finnish Registry of Transcatheter and Surgical Aortic Valve Replacement for Aortic Valve Stenosis (FinnValve) registry, 19.6% of the patients who underwent 2,130 TAVI had a history of cancer, and 5.3% had active cancer. The risk of cancer increases with age, and the difference in cancer prevalence between our study and those studies is probably due to the age difference. The ages of the patients in our study were younger than those in previous studies. In the studies of Tabata et al.[10] and Biancari et al.,[11] prostate, breast, and colorectal cancers ranked the first place, whereas chronic lymphocytic leukemia and bladder cancers were seen after the prostate and colorectal cancers in our study.

Furthermore, Watanabe et al.[12] reported the outcome of 47 Japanese cancer patients treated with TAVI. Consistent with our findings, 30-day and one-year results showed TAVI to be as safe and effective as in non-cancer patients. However, as in our study, the fact that this study was conducted in a small population and ethnic differences must be kept in mind.[12] Our results are, in contrast to the study by Mangner et al.,[13] reported a similar 30-day mortality rate, but one-year mortality was higher in cancer than in non-cancer patients who underwent TAVI (n=99). Similarly, they showed a limited cancer disease state associated with better survival than an advanced disease status (active or cured). A study based on the TAVI in Oncology Patients with AS (TOP-AS) registry revealed that TAVI in cancer patients is associated with similar short-term, but worse long-term prognosis than patients without cancer.[14] The 30-day mortality was found to be identical to non-cancer patients, but one-year mortality was higher in cancer patients (15% vs. 9%; $p<0.001$). Another critical finding was that Stage 3-4 malignancy was a strong mortality predictor, whereas Stage 1-2 disease was not associated with higher mortality rates, compared to non-cancer patients.

Current guidelines indicate that patients with <12-month predicted life expectancy due to non-valvular comorbidities should be excluded from TAVI. Based on the present findings, we can speculate that individual evaluation is necessary to obtain the benefit of the TAVI in cancer patients and that cancer should not be an absolute contraindication for TAVI in cancer patients with symptomatic AS. The Heart Team's final decision should depend on the state of cancer, stage of cancer, and non-cardiac comorbidities. Based on all these data, limited-stage and cured cancer patients have similar short and long-term mortality rates, compared to non-cancer patients.

In our study, there was no significant increase in the mean gradients in both groups after TAVI. However, in the study of Tabata et al.,[10] the mean baseline gradients for cancer and non-cancer patients were 7.40 (range, 4.95 to 10.00) mmHg and 8.05 (range, 5.78 to 11.60) mmHg, respectively ($p=0.021$). The mean gradients increased from 7.40 (range, 4.95 to 10.00) mmHg to 8.10 (range, 5.80 to 11.20) mmHg in the cancer group ($p=0.012$), while the mean gradients did not increase in the non-cancer group. In our study, although there was no long-term echocardiography follow-up as much as this study, the increased mean gradient in this study was not severe and hemodynamically acceptable. The mean gradient increase in cancer patients may be due to hypercoagulopathy and subclinical leaflet thrombosis. Further studies are needed to draw firm conclusions on this subject.

Nonetheless, the present study has several limitations. First, this is a single-center, retrospective study. Second, detailed information about the cancer stages, treatment, and duration of the patients are missing. Third, the number of cancer patients is

relatively small and the long-term follow-up data about mortality, bleeding, infective endocarditis or leaflet thrombosis of the patients are limited. Above all, analysis of the statistical differences between cancer and non-cancer groups was challenging due to the regional cancer population. Finally, the number of active cancer patients is limited, compared to previous studies.

In conclusion, our study results suggest that the transcatheter aortic valve implantation procedure is safe and feasible in active and cured cancer patients, with similar short-term and mid-term mortality and peri-procedural complication rates, compared to non-cancer patients. However, further large-scale, prospective, randomized trials are needed to confirm these findings in this patient population.

Declaration of conflicting interests

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