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Outcomes after transcatheter aortic valve replacement in cancer survivors with prior chest radiation therapy: an updated systematic review and meta-analysis

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Abstract

Clinical outcomes for TAVR in cancer survivors with prior chest radiation therapy (C-XRT) who develop symptomatic aortic-valve stenosis are not adequately assessed in major clinical trials leading to conflicting results. Hence, we conducted this meta-analysis to evaluate the, safety, efficacy, and mortality outcomes of cancer survivors with prior C-XRT undergoing TAVR. MEDLINE and Scopus were searched up to March 2024. Observational studies and randomized controlled trials comparing severe aortic stenosis patients with and without prior C-XRT undergoing TAVR with at least one outcome of interest were shortlisted. Data were analyzed using random-effects model to derive weighted mean differences, and risk ratios with 95% confidence intervals. Six studies with 6,191 patients (278 C-XRT and 5,913 no-C-XRT) were included. All-cause mortality at 30-day (RR 1.63, $p=0.12$) and 1-year interval (RR 1.59, $p=0.08$) showed no significant differences with prior C-XRT versus no-C-XRT. Worsening CHF was the only post-procedural safety outcome significantly higher in patients with prior C-XRT (RR 1.98, $p=0.0004$) versus no-C-XRT. The efficacy end-points i.e., improvement in LVEF (MD 1.24; -0.50, 2.98), and aortic valve gradient (MD -0.63; -1.32, 0.05) were not significantly different. TAVR has similar all-cause mortality, efficacy and safety (except CHF worsening) among cancer survivors with and without a prior history of C-XRT.

Introduction

Heart failure (HF) due to radiation-induced aortic stenosis (AS) manifests as the most frequent late complication of chest radiation therapy (C-XRT) in cancer patients [1]. Despite the recent technological advances in cardiac-sparing radiation therapies, patients presenting with symptomatic cardiotoxic effects of radiation remain a topic of concern for clinicians. An average survival rate of <2 years in patients with untreated symptomatic AS, and the lack of effective non-invasive treatment options makes satisfactory clinical surveillance pertinent in the survival of such patients [2, 3]. Surgical aortic valve replacement (SAVR) is indicated in patients with AS,

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however patients with a history of C-XRT pose complexity, owing to radiation-induced mediastinal fibrosis, and calcification of cardiac valves [2, 4]. Another minimally invasive technique for AVR i.e., transcatheter aortic valve replacement (TAVR) might constitute a potential treatment option in this cohort, however, its utilization is limited by the small number of clinical studies comparing safety, and efficacy outcomes between cancer survivors with vs. without a history of C-XRT in previous literature.

A meta-analysis conducted by Sharma et al. concluded TAVR to show similar safety, and efficacy profile in AS patients with vs. without C-XRT, however the study does not include many recent clinical studies resulting in much smaller pooled patient populations [5]. In accordance with a recent retrospective analysis by Kherallah et al. patients with a history of C-XRT demonstrate higher rates of respiratory failure, and need for permanent pacemaker implantation (PPM) [6]. Whereas another analysis by Mohanty et al. showed directly contrasting results with no significant differences between C-XRT vs. non-C-XRT groups in terms of PPM following TAVR among AS patients [7]. Hence, we conducted this updated meta-analysis pooling all recent clinical studies to show a holistic and comprehensive clinical evaluation on the efficacy and safety of TAVR among AS patients with vs. without C-XRT.

Methods

This systematic review and meta-analysis was conducted following the Preferred Reporting Items for Systematic reviews and Meta-Analysis (PRISMA) guidelines, Cochrane, and Assessing the methodological quality of systematic reviews-2 (AMSTAR-2) guidelines [8–10].

Data sources and search strategy

Two independent investigators (FY and AM) conducted a systematic literature search using electronic databases, including MEDLINE (PubMed), Scopus, and Cochrane Central, from inception till March 2024. Online databases such as www.clinicaltrials.gov, medRxiv.org, and conference proceedings and presentations were also searched to identify grey literature. The following MeSH term were used to maximize the sensitivity of the search: ('transcatheter aortic valve implantation' OR transcatheter aortic valve replacement' OR 'TAVI OR 'TAVR') AND ('malignancy' OR 'cancer survivors') AND ('radiation therapy'). The detailed search strategy for each database is provided in Table S1.

Study selection and inclusion criteria

All articles initially retrieved from the systematic search of the electronic databases were transferred to Endnote Reference Library (Version X7.5; Clarivate Analytics, Philadelphia, Pennsylvania) software, where duplicates were identified and excluded. Additionally, the studies were screened to ensure no two studies used data from the same database or registry to avoid duplication. Two investigators (FY and AM) independently shortlisted the remaining articles based on the titles and abstracts and subsequently screened the full-texts of the articles to assess relevance. Any discrepancy was settled by consulting a third investigator (VV) until a consensus was reached. The reference lists of all eligible articles were also screened manually for further identification of potentially relevant articles. Articles were shortlisted based on the following eligibility criteria; (a) Comparative studies between patients with severe AS who were exposed to C-XRT vs. patients with severe AS without C-XRT, (b) studies with at least one of the following outcomes: all-cause mortality at 30-day and 1-year follow-up, safety outcomes at 30-day follow-up according to Valve Academic Research Consortium-2 definitions (stroke, major bleed, access-related vascular complications, and need for a pacemaker), and efficacy outcomes (post-procedural mean aortic valve gradient and left ventricular ejection fraction), worsening congestive heart failure and acute kidney injury, (c) retrospective, prospective cohorts, and randomized controlled trials (RCTs). Cancer survivors were defined as patients with a history of thoracic malignancy for which they underwent radiotherapy (along with other therapies, if indicated) and their disease was in remission at the time of TAVR. Studies were excluded if they were; (a) case-reports, review articles, editorials, and expert opinions, (b) studies with a sample size < 10 patients, and age < 18 years, (c) studies not reporting the outcomes of interest.

Data extraction and quality assessment

Two independent investigators (FY and AM) conducted data extraction of the relevant articles shortlisted. In each study following data was extracted: the leading author's last name, year of publication, study design, country of origin, the number of participants in each group, general patient characteristics including mean age, comorbidities, body mass index (BMI), and all outcomes of interest. Two independent investigators (FY and AM) performed the quality assessment to gauge the validity and reliability of the included studies. The risk of bias of observational studies was evaluated independently using the Newcastle-Ottawa Scale (NOS) [11] which assesses the selection, comparability, and outcome assessment biases. The investigators assessed the risk of bias for the included studies and assigned a score for each category. Further, the score assigned to each study was categorized into ratings. No publication bias assessment was carried out as there were less than ten studies included in the meta-analysis as per the Cochrane guidelines [10].

Statistical analysis

This meta-analysis was conducted using Review Manager (RevMan) [Computer program] Version 5.4 Cochrane Collaboration. A random-effects model was used to calculate weighted mean differences (WMDs) for continuous variables using the inverse variance method, whereas the Mantel-Haenszel (MH) method was used to pool odd ratios (ORs) with a 95% CI for the dichotomous variables. The Higgins I^2 index was calculated to examine heterogeneity across the included studies. The I^2 values of 0–25% were labeled as low, 25–50% as mild, 50–75% as moderate, and 75% above as substantial heterogeneity. For each clinical outcome, forest plots were generated to show the relative effect sizes of the comparison groups. A leave-one-out sensitivity analysis was performed to determine if a single study had disproportionate effects on the pooled estimates. A p-value ≤ 0.05 was considered significant in all cases.

Results

A total of 442 potentially relevant citations were identified and screened from the initial search. After the removal of duplicated studies, we retrieved 100 full-text articles for evaluation of which six eligible observational studies were ultimately included in the analysis [6, 7, 12–15]. The PRISMA flow chart outlines the systematic literature search and study selection process in Fig. 1. A total of 6,191 patients were included of which 278 patients were in the prior C-XRT group, and 5,913 patients in without prior C-XRT group. The mean age of the participants was 82.2 years. The demographic characteristics, and study design of the included studies are presented in Table 1.

The most common indication for radiation in C-XRT group included breast cancer, Hodgkin lymphoma, non-Hodgkin lymphoma, lung cancer, esophageal cancer, thymoma, seminoma and throat cancer among others. Only 4 out of 6 included studies reported data on the type of cancer the patients were treated for in the C-XRT group [6, 12, 14, 15]. The median time between chest radiation therapy and TAVR ranged between 18 and 30 years. However, the radiation dosage was infrequently reported in the included studies. For breast cancer cases, Dijos et al. included all patients with left-sided malignancies whereas 64% of the breast cancer patients in the study by Agrawal et al. had left-sided malignancy. The remaining studies did not present data on the laterality of the tumor. The data has been summarized in detail in Table 2.

Methodological quality assessment of the included studies

Quality assessment of the included studies showed that four studies had a good quality, while two (Bouleti et al. and Dijos et al.) were of fair quality on the NOS. The summary of the quality assessment domains from the included studies is shown in Table S2. Overall, the quality assessment showed a robust methodology of the included observational studies.

Primary outcome

30-day mortality was reported in all six included studies, and 1-year mortality was reported in the five included studies except for Dijos et al. All-cause mortality at both the 30-day (OR 1.63, 95% CI 0.89–2.98, $p=0.12$; $I^2=0\%$) and 1-year interval (OR 1.32, 95% CI 0.92–1.90, $p=0.13$; $I^2=0\%$) showed no significant association between patients with prior C-XRT as compared to patients without C-XRT. The forest plots for all-cause mortality at 30-day and 1- year follow-up durations are shown in Fig. 2.A and B, respectively.

Safety outcomes (at 30-day follow-up)

All six studies reported stroke as an outcome, and pooled analysis showed no significant differences (OR 1.76, 95% CI 0.67 to 4.62, $p=0.25$; $I^2=36\%$) between C-XRT vs. no C-XRT groups. Similarly, no significant differences were noted in the incidence of major bleeding events (OR 1.28, CI 0.75 to 2.18, $p=0.37$; $I^2=0\%$) between the two groups (Fig. 3.A and **3**.B). Access-related vascular complications were reported by five studies and demonstrated no statistically significant differences between the comparison groups (OR 1.24, CI 0.76 to 2.04, $p=0.39$; $I^2=0\%$) (Fig. 3.C). Need for PPM was reported by all six studies; however, we included data from five studies as Agrawal et al. did not report the PPM outcome at the 30-day follow-up. According to pooled analysis, there was no statistically significant difference in the need for a pacemaker implantation (OR 1.26, CI 0.69 to 2.31, $p=0.45$; $I^2=45\%$) (Fig. 4A). Post-procedural worsening of congestive heart failure was reported in five studies except for Mohanty et al. The pooled analysis showed significantly higher rates of worsening congestive heart failure (CHF) in patients with prior C-XRT than those without C-XRT (OR 1.98, CI 1.36 to 2.88, $p=0.0004$; $I^2=0\%$) (Fig. 4B). Lastly, acute kidney injury was reported by all six studies, and showed no statistically significant differences between those with prior-CXT vs. without (OR=0.7, CI 0.20 to 2.46, $p=0.58$; $I^2=53\%$) (Fig. 4C).

Efficacy outcomes

Left ventricular ejection was reported in four studies, and pooled analysis showed no statistically significant difference between the comparison groups (WMD=1.24, CI -0.50 to 2.98, $p=0.16$; $I^2=34\%$) (Fig. 5.**A**). Similarly, no significant differences were noted in rates of mean aortic valve gradient between patients with vs. without C-XRT (Mean difference = -0.63, CI= -1.32 to 0.05, $p=0.07$; $I^2=53$) (Fig. 5.B).

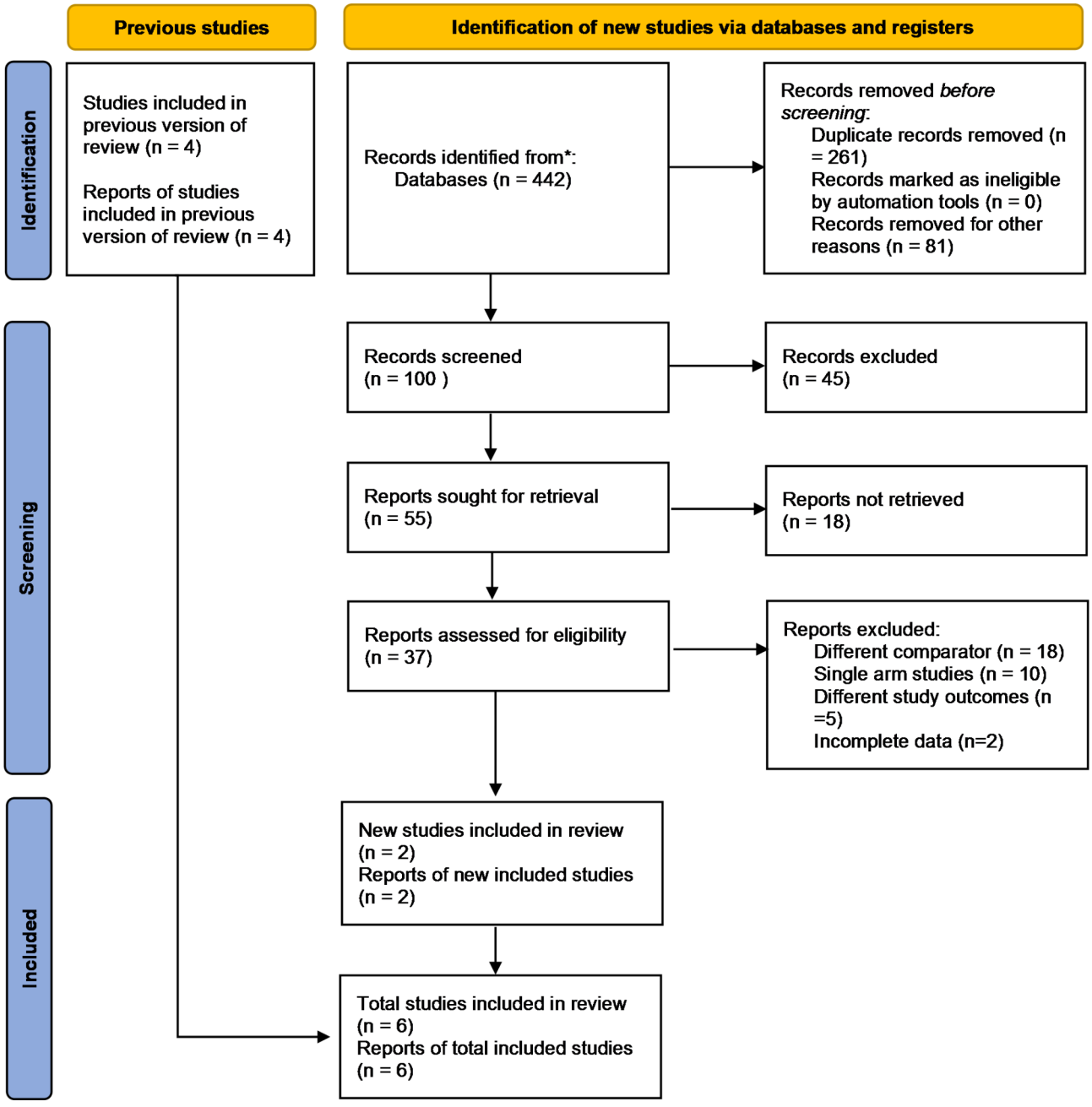

Fig. 1 PRISMA flow diagram

Discussion

Chest radiation exposure associated with severe valvular disease commonly aortic stenosis has been under the area of active research recently owing to the lack of plausible data, and the dilemma of opting for a suitable surgical approach for valvular repair after the consequent development of challenges, such as mediastinal fibrosis and pericardial constriction rendering the feasibility of surgical intervention questionable despite the necessity. The lack of significant clinical trials and credible research data leaves cancer survivors with debatable options for suitable surgical intervention, the judgment mostly based on the prognosis of cancer itself. The findings of our updated meta-analysis appraising the outcomes of TAVR in patients with versus without prior C-XRT had discerned notable findings regarding short, and long-term mortality, safety, and efficacy of the procedure. We demonstrated TAVR to be safe in cancer survivors with a history of C-XRT, with similar all-cause mortality at 30-days, and 1-year interval, post-procedural safety in terms of stroke, and major bleeding events, as well as efficacy of the procedure in improving LVEF, and mean

Table 1 Values presented as n (%), mean (SD), or median (25th-75th percentiles) (*) indicates p valve < 0.05 for patients in the radiation group (C-XRT) compared to the control group BMI body mass index, STS Surgical thoracic society risk score, LVEF Left ventricular ejection fraction, AV aortic valve, NR not reported, PSM Propensity score matched

	Groups	Dijos, et al. [15]	Bouleti, et al. [12]	Gajanana, et al. [13]	Agrawal, et al. [14]	Kherallah, et al. [6]	Mohanty, et al. [7]
Sample size	C-XRT	19	26	44	75	50	64
	Control	179	26	1150	535	100	3923
	Total	198	52	1194	610	150	3987
Demographics							
Age	C-XRT	68.3 (11.7) *	73.4 (22.3)	76 (13) *	81.64 (7.8)	Age > 65: 35 (70)	72.1 (11.5)
	Control	82.5 (6.6)	73.3 (15.3)	82 (8)	82.6 (8.0)	Age > 65: 75 (75)	82.2 (7.6)
Male sex	C-XRT	7 (36.84)	13 (50)	10 (23) *	29 (38.7)	21 (42)	29 (45.3)
	Control	101 (56.4)	13 (50)	583 (51)	291 (54.4)	42 (42)	2228 (56.8)
BMI ((kg/m^2)	C-XRT	25.9 (5.1)	21.9 (6.2) *	29.1 (8.9)	27.14 (6.3)	28.4 (6.8)	25.6 (7)
	Control	27.1 (5.7)	27.6 (6.9)	28.2 (8.6)	28.11 (6)	28.2 (6.3)	27.2 (7.4)
Comorbid conditions							
Hypertension	C-XRT	9 (47.3) *	12 (46)	37 (86)	66 (88)	NR	55 (85.9)
	Control	139 (77.6)	22 (85)	1062 (93)	476 (88.9)	NR	3633 (92.6)
Diabetes mellitus	C-XRT	1 (5.3) *	0 (0)	13 (31)	31 (41.3)	21(42)	16 (25.0)
	Control	56 (31.3)	7 (27)	392 (34)	176 (32.5)	42(42)	1385 (35.3)
Coronary Artery Disease	C-XRT	9 (47.3)	14 (54)	NR	50 (66.7)	NR	46 (71.9)
	Control	104 (58.1)	12 (46)	NR	307 (57.3)	NR	3025 (77.1)
Prior stroke	C-XRT	0 (0)	1 (4)	4 (9)	10 (13.3)	NR	5 (7.8)
	Control	11 (6.1)	2 (8)	125 (12)	53 (9.9)	NR	734 (18.7)
Control Risk scores and Echocardiographic characteristics							
STS score (%)	C-XRT	NR	5.0 (3.2)	7 (4)	8.1 (4.2)	7.0 (4.9)	5.7 (3.3)
	Control	NR	4.7 (5.7)	8 (5)	8.1 (4.2)	7.2 (5.8)	7.5 (4.1)
LVEF (%)	C-XRT	57 (11.3)	60 (15)	53 (11)	55.6 (12.4)	NR	51.6 (14.6)
	Control	53.8 (14.4)	60 (15)	52 (13)	54.46 (13.1)	NR	55.2 (13.3)
Mean AV gradient (mm Hg)	C-XRT	47.9 (15.5)	47.0 (16)	41 (9) *	43.06 (13.7)	37.2 (10.6)	41.7 (14.4)
	Control	45.9 (15.8)	52.0 (19)	45 (13)	40.87 (15.5)	37.2 (10.6)	44.3 (13.9)

Table 2 Data on the median time duration between chest radiation therapy and TAVR, radiation dose and type of malignancies in C-XRT group

	Dijos, et al. [15]	Bouleti, et al. [12]	Gajanana, et al. [13]	Agrawal, et al. [14]	Kherallah, et al. [6]	*Mohanty, et al.* [7]
Median time between radiation and TAVR (years)	> 10	30 (14–40)	-	19.0 (Mean 20.1 ± 4.9)	18 [14–34]	-
Median cumulative radiation dose (Gray)	-	-	-	-	44 [41–54]	-
Type of cancer			-			-
Breast cancer	7/19 (36.8%)	11/26 (42%)		33/75 (44%)	21/50 (42%)	
Hodgkin lymphoma	8/19 (42.5%)	11/26 (42%)		23/75 (31%)	19/50 (36%)	
Non-Hodgkin				5/75 (7%)	1/50 (2%)	
Lung cancer	2/19 (10.5%)	2/26 (8%)		11/75 (15%)	4/50 (8%)	
Esophageal cancer					1/50 (2%)	
Thymoma					1/50 (2%)	
Seminoma		1/26 (4%)			1/50 (2%)	
Throat cancer		1/26 (4%)				
Others				2/75 (3%)		

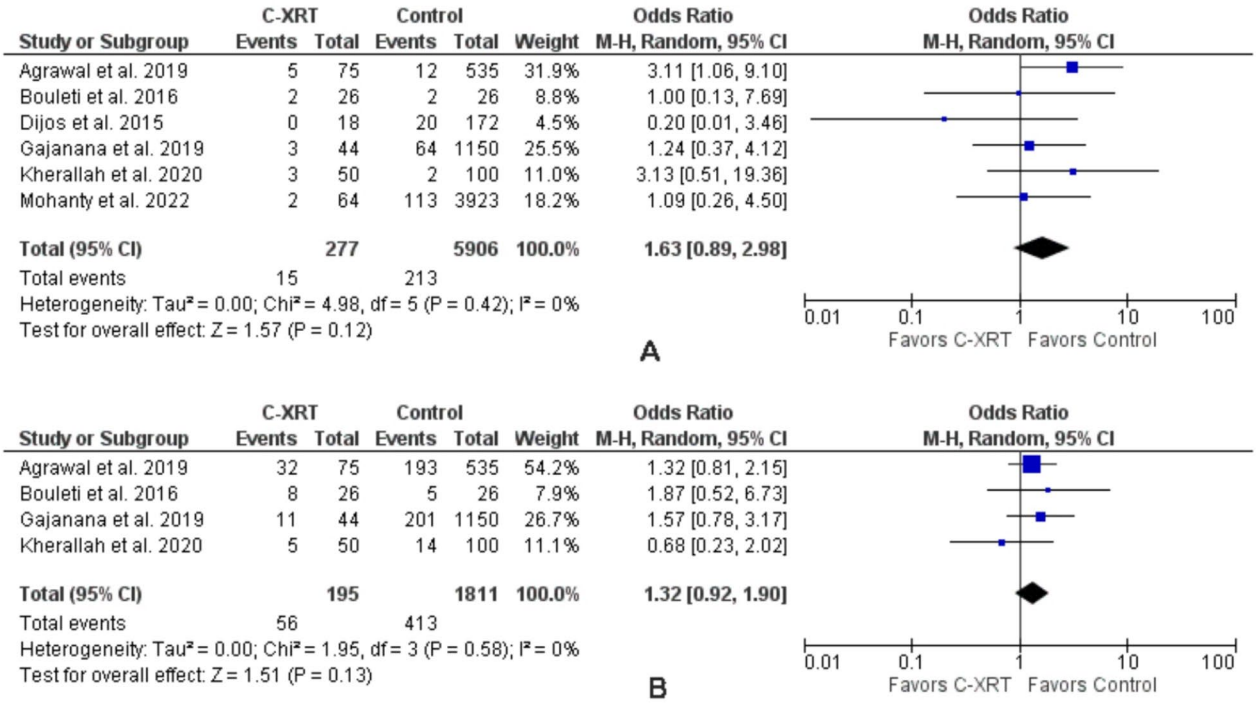

Fig. 2 Comparison of (**A**) 30-day and (**B**) 1-year all-cause mortality in cancer patients with or without C-XRT

aortic valve gradient. We further found that exacerbation of CHF post-procedurally was higher among patients with C-XRT compared to the control groups.

Our updated analysis showed that the mortality rate at both the 30-day, and 1-year interval was similar in the radiation group compared to the control group. This is in contrast with the findings of a previous meta-analysis by Zafar et al. which indicated higher mortality at 1-year follow-up among TAVR patients with prior C-XRT [16]. These conflicting findings can be explained by the addition of two new large-scale observational studies by Kherallah et al., and Mohanty et al. both of which followed cancer survivors for a duration of 2-years and found no significant differences in all-cause death between those with prior C-XRT, and control groups [6, 7]. However, previously published observational studies have indicated radiation therapy [14], and malignancy progression as potential factors for higher long-term mortality outcomes for TAVR in the cancer population [17]. A recent study by Strange et al. found that the risk of 1-year mortality in patients with the low burden of co-morbidities undergoing TAVR was found to be 5.5%, and contrarily, in patients with high co-morbidity burden was found to be 25% [17]. Together with this, Siddiqui et al., also found that patient baseline co-morbidities are a considerable factor in the readmissions of patients who underwent TAVR and survived their index hospitalizations [18] putting forward that the risk factor assessment for underlying co-morbidities in cancer survivors considered for TAVR may remarkably allow physicians to predict a far better long-term prognosis.

Individual phenotyping of patients and consideration of appropriate personalized rehabilitation with effective monitoring may improve co-morbidity associated with increased long-term mortality after TAVR together with better assessment of prognosis. Further studies are suggested to evaluate the incidence and type of comorbidity most associated with poor post-procedural prognosis. Different peri-procedural management plans can be explored and tailored to the individual phenotyping of patients according to demographic and clinical factors to increase the probability of long-term survival. In addition, further studies on co-morbidities particularly associated with cancer survivors such as cardio metabolic co-morbidities may be of additional benefit in drawing better conclusions regarding the prognosis of TAVR in cancer survivors.

The post-procedural safety outcomes including stroke, major bleeding events, access-related vascular complications, PPM implantation, and acute kidney injury at 30-days were similar in both groups. It has been previously established that TAVR can be theoretically a better surgical intervention in patients with prior C-XRT due to its advanced, and minimally invasive technique bearing advantage over open-heart surgery in patients with extensive chest radiation, and mediastinal fibrosis. These

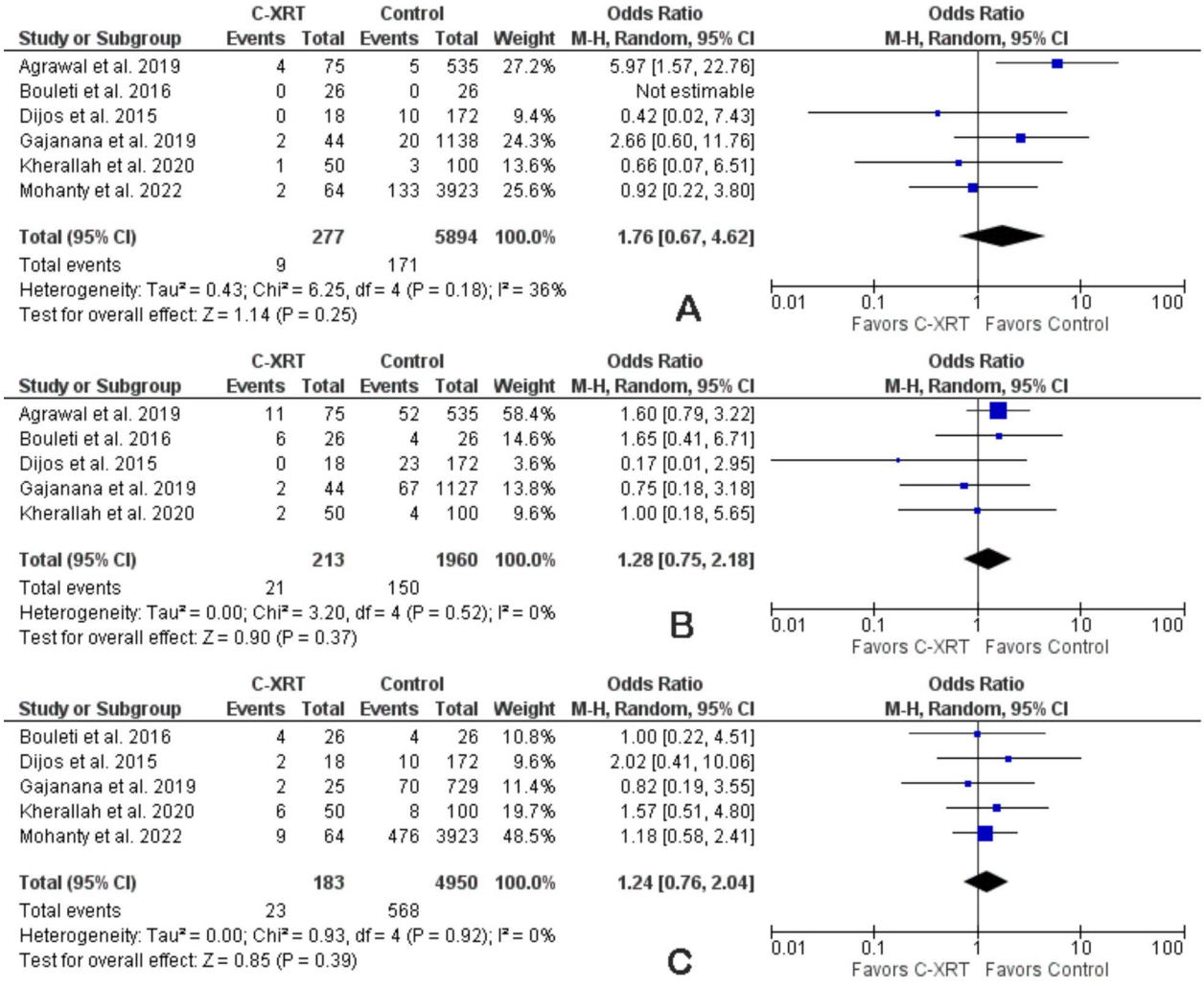

Fig. 3 Forest plot summarizing the pooled analyses of safety outcomes at 30-day follow-up between cancer survivors with vs. without history of C-XRT undergoing TAVR. (**A**) Stroke, (**B**) Major bleeding events, (**C**) Assess related vascular complications

better peri-procedural safety outcomes can be linked to the recent advancements in TAVR techniques, closer monitoring, and anticoagulative therapy that has particularly reduced the incidence of stroke in this cohort [16]. Our analysis revealed no significant differences in the incidence of PPM implantation between the two groups. These findings parallel the observations from the PARTNER 2 registry which analyzed 3987 cancer survivors undergoing TAVR and found no difference in rates of PPM implantation [7]. In contrast, the study by Agrawal et al. indicated higher incidence of pacemaker implant in cancer survivors with prior C-XRT at a mean follow-up of 17 months [14]. C-XRT is also notoriously reported to cause damage to the conduction pathways via fibrosis consequently leading to arrhythmias. Hence, watchful monitoring is essential in these patients for earlier detection, and treatment of these conduction abnormalities. The remarkably higher incidence of exacerbation of post-procedural CHF was a characteristic finding in patients with prior C-XRT despite paralleling aortic valve gradients, and LVEF before and after TAVR as the control groups. Several possible causative factors can be put forward for the finding, including the radiation exposure associated diastolic dysfunction, contribution of post-procedural anemia, blood transfusions, pulmonary hypertension, and atrial dilation in worsening of heart failure while also considering the cardiotoxic effect of some chemotherapeutic agents delineating that the plausible exacerbation may be possibly caused by independent post-procedural, and post-radiotherapeutic phenomena rather than the procedure itself.

There are a few limitations of our study that warrant consideration. First, all of the studies included in our analysis were observational, and hence associated with confounders, and risk of bias. Randomized control trials comparing TAVR with standard medical therapy

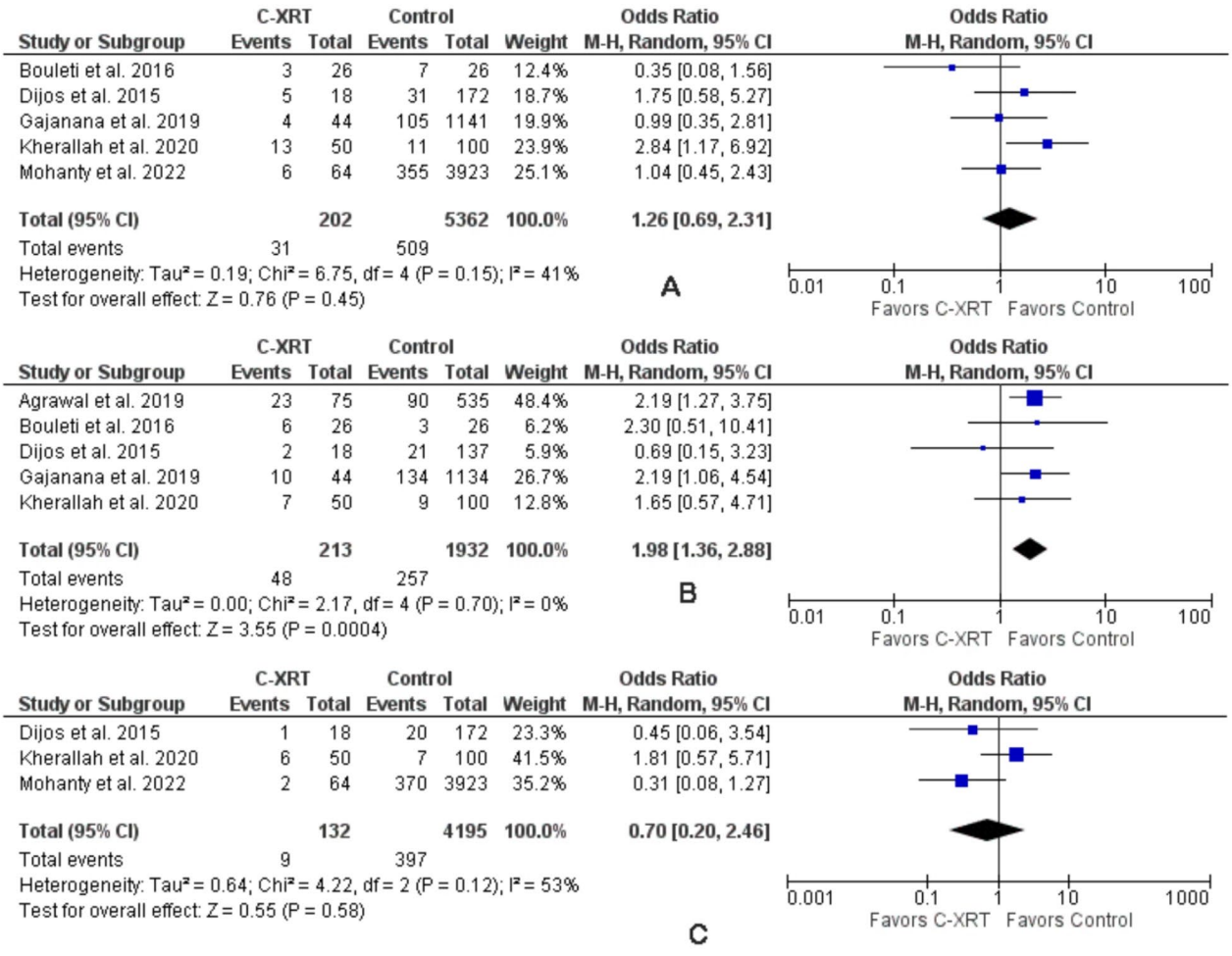

Fig. 4 Forest plot summarizing the pooled analyses of all safety outcomes at 30-day follow-up between cancer survivors with vs. without history of C-XRT undergoing TAVR. (**A**) Need for permanent pacemaker implantation, (**B**) Post-procedural worsening of congestive heart failure, (**C**) Acute kidney injury

in cancer survivors are critical to resolve this clinical enigma. Second, our study population displays a widely heterogeneous, and relatively smaller number of patients with different thoracic malignancies, variable therapies, and underlying comorbidities. Thus, it was difficult to stratify them based on types of malignancy. This would obligate access to an outsized patient database, which is not presently available. Third, we could not evaluate the influence of the amount of radiation dosage, the time duration between last chest radiation therapy and TAVR and laterality of the tumor on the clinical outcomes due to limited data reported in the included studies. The studies also did not report data for cancer-related and non-cancer specific deaths hence this could not be evaluated for all-cause mortality. Fourthly, we were unable to compare the outcomes of TAVR versus surgical aortic valve intervention in cancer survivors with prior C-XRT due to lack of optimal number of available studies to analyze them meta-analytically. Finally, we cognize that data on long-term valve dysfunction are essential, but unfortunately, they were not conferred in the included studies.

Conclusion

Our updated meta-analysis comparing clinical outcomes of TAVR among patients with versus without prior chest radiation exposure demonstrated similar rates of all-cause mortality at 30-days and 1-year follow-up, safety in terms of stroke, major bleed, CHF, vascular complications, PPM implantation, and efficacy including LVEF and mean aortic valve gradients between the two groups. However, large-scale RCTs comparing TAVR with standard medical therapy and SAVR are needed in this underrepresented patient subpopulation to establish conclusive evidence.

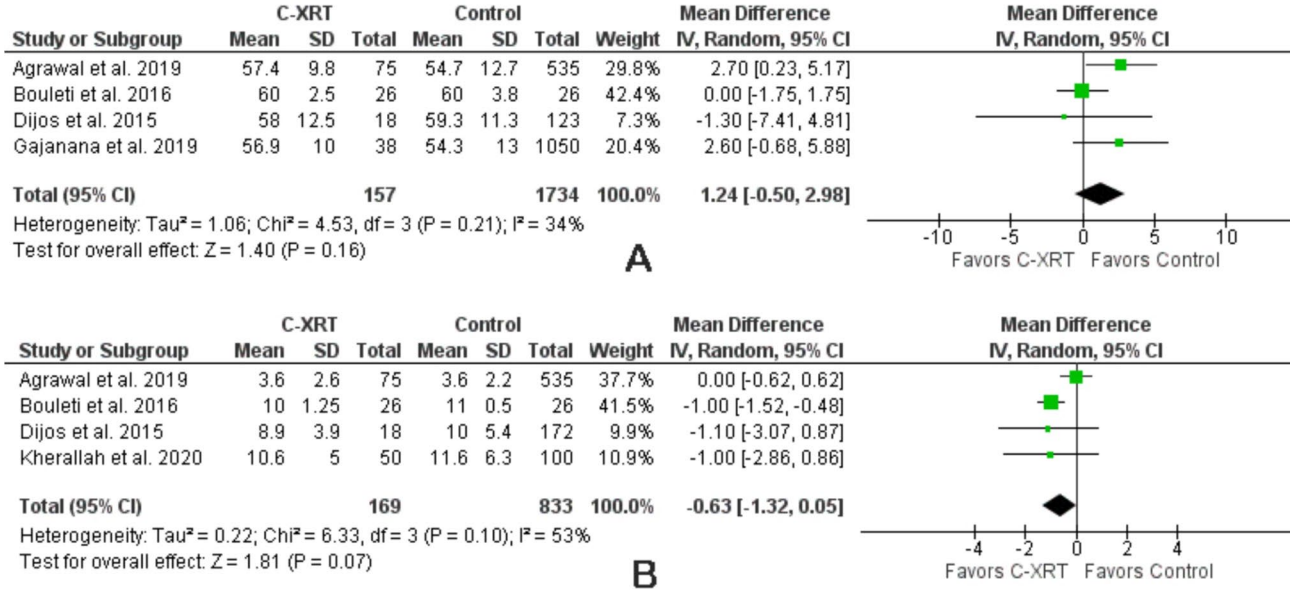

Fig. 5 Forest plot summarizing the pooled analyses of all efficacy outcomes between cancer survivors with vs. without history of C-XRT undergoing TAVR. (**A**) Left ventricular ejection, (**B**) Mean aortic valve gradient

Supplementary Information

The online version contains supplementary material available at https://doi.org/10.1186/s40959-024-00265-7.

Supplementary Material 1

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Author contributions
FY, and AM participated in the conceptualization, data curation, investigation, methodology, project administration, resources, supervision, validation, visualization, and writing of the original draft. MU, MTA, VV, YK participated in the formal analysis, project administration, and writing – review & editing. AS, AVV, CA participated in the conceptualization, formal analysis, investigation, methodology, project administration, software, supervision, validation, visualization, and writing – review & editing.

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Data availability
The datasets used and/or analyzed during the current study available from the corresponding author on reasonable request

Declarations

Ethics approval
Institutional Review Board Approval was not required for this study as all data utilized was publicly available, and does not include human participants

Consent for publication
Not applicable.

Competing interests
The authors declare no competing interests.

Disclosures
None.

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