European real world transcatheter aortic valve implantation: Systematic review and meta-analysis of European national registries.

Mohamed Zeinah*, FRCS [1,2], MD; Mohamed Elghanam, FRCS, MD [1]; Umberto Benedetto, MD, PhD [2].

Authors affiliation: (1)= Ain Shams university, Cairo, Egypt. (2) = Oxford heart centre, UK.
*Corresponding author: Mohamed Zeinah, Cardiothoracic surgery department, Faculty of medicine, Ain Shams University, Abbassieh, 11381 Cairo, Egypt. Tel.: +2 0122 4063718; Fax +2 02 24820416. email: mohamed.zeinah@ouh.nhs.uk.
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ABSTRACT

OBJECTIVES: Transcatheter aortic valve implantation (TAVI) has been adopted rapidly in Europe despite the paucity of randomized studies. TAVI registries represent a real-world scenario thus providing the evidence for the treatment of high-risk patients. We undertook a meta-analysis of published European national TAVI registries to assess current results of TAVI technologies in Europe.
METHODS: Electronic databases were searched. The review focused on the comparison of the following TAVI technologies: transfemoral (TF) and transapical (TA) SAPIEN and Core Valve implantation. Individual event rates for outcomes of interest were pooled using a mixed effect model.
RESULTS: A total of 7 European national TAVI registries (UK, Swiss, Belgium, Italy, Spain, France, Germany) were identified including a total of 9786 patients who received TF SAPIEN (n=2885), TA SAPIEN (n=2252) and Core Valve (n=4649) implantation. Pooled incidence of 30 days mortality was 0.08 [95% Confidence Interval (CI): 0.05-0.11], 0.12 [95%CI: 0.07-0.19] and 0.06 [95% CI: 0.03-0.11] for TF SAPIEN, TA SAPIEN and Core Valve respectively (test for subgroup difference P=0.18) and high heterogeneity across European country was found. Pooled incidence of stroke was comparable among the TAVI technologies (test for subgroup difference P=0.79) as well as the incidence of post procedure paravalvular leak ≥ 2 (P=0.9). Core Valve increased the likelihood of pacemaker implantation requirement (test for subgroup difference P<0.0001).
CONCLUSIONS: Trans-vascular TAVI approaches were associated with a lower early mortality regardless of the type of device used. There was a marked heterogeneity among European countries for early mortality.
Keywords: Transcatheter aortic valve implantation, aortic stenosis, registry

INTRODUCTION

Since Dr Alain Cribier pioneered the first transcatheter aortic valve implantation (TAVI) procedure in 2002 [1], this relatively new technique has been used extensively in Europe. Based on the compelling evidence from the randomized Placement of Aortic Transcatheter Valves (PARTNER) A and B cohort [2,3], TAVI is now considered standard of care for extreme risk and inoperable patients and is an alternative to surgery for high risk patients with symptomatic aortic stenosis [4]. However, patients enrolled were highly selected, which does not reflect a clinical real-world situation. In a randomized controlled trial, it is reasonable to exclude patients presenting with co-morbidities or

anatomical constraints to avoid confounding, but it is therefore difficult to extend the major finding of the study to a real-world patient population. Nevertheless, patients at high-risk or inoperable due to co-morbidities driving the surgical risk score or frailty are captured by mixed national registries, which therefore provide the evidence for the treatment of high-risk patients (with co-morbidities and anatomical constraints) in daily clinical practice [4].

Furthermore, mixed national registries report country specific results, which may be affected by variations in national health policy and practice, device performance and definitions thus accounting for otherwise inexplicable differences in outcome and complications. Therefore, we aimed to get insight into the role of TAVI in the treatment of high-risk patients with aortic stenosis in Europe by conducting a meta-analysis of European national registries focusing on three different TAVI technologies widely adopted: the transfemoral and transapical balloon-expandable Edwards SAPIEN transcatheter heart valve (Edwards Life sciences, Irvine, CA, USA) and the self-expanding Medtronic Core Valve (Medtronic, Minneapolis, MN, USA).

MATERIAL AND METHODS

The present review was performed according to the Cochrane Collaboration and PRISMA statements [5]. Studies included in the present meta-analysis met the following criteria: (1) European national registry reporting outcomes of patients undergoing TAVI; (2) transfemoral (TF SAPIEN) and/or transapical (TA SAPIEN) balloon-expandable Edwards SAPIEN transcatheter heart valve and/or the self-expanding Medtronic Core Valve were used. Non-English language, review articles, and editorials were excluded. Care was taken to ensure that studies selected did not result in duplication of data. Studies that did not separate results for TF SAPIEN, TA SAPIEN and Core Valve were excluded.

A literature search was done on 1 September 2014 using MEDLINE, EMBASE, and Web of Science to identify relevant articles. Search terms used the controlled vocabularies of MEDLINE and EMBASE alone or in combination with text words including "transcatheter aortic valve implantation", "TAVI", "registry", "Europe". References from the selected studies were also manually searched to avoid missing any potentially suitable articles.

Our primary endpoints were: mortality within 30 days and 1 year, incidence of stroke, pacemaker implantation, and aortic paravalvular leak ≥2. Two reviewers (U.B., C.N.) independently screened all studies for inclusion. Disagreements were resolved by consensus.

Statistical analysis: Agreement between reviewers regarding study inclusion was assessed using the Cohen k statistic. Mixed effects meta-analysis of single proportions using the DerSimonian-Laird estimate was used to calculate overall proportions of outcomes using different TAVI technologies. I^2 statistic was used to estimate the percentage of total variation across studies, which is due to heterogeneity rather than chance. Suggested thresholds for heterogeneity were used, with I^2 values of 25% to 49%, 50% to 74%, and 75% or greater, indicative of low, moderate, and high heterogeneity [6]. Cochrane Q statistic was used as test for subgroup differences (random effects model). By means of multivariate meta-regression (mixed effect model), the effect of different TAVI technologies on investigated outcomes was adjusted for the following confounding factors: average patient risk profile using average Logistic Euroscore [7], European country, total number of centres involved and funding by manufacturer. R^2 was used to estimate the amount of heterogeneity accounted for in the mutivariate model. Publication bias was assessed using Begg & Mazumdar test. Trim-and-fill method was used for estimating and adjusting for the number and outcomes of missing studies. A P value less than 0.05 was used as the level of significance and 95% confidence intervals (95%CI) have been reported where appropriate. R version 3.1.0 (R Core Team (2014). R: A language and environment for statistical computing. R Foundation for Statistical Computing, Vienna, Austria. URL http://www.R-project.org/) and meta package (Guido Schwarzer

(2014). meta: Meta-Analysis with R. R package version 3.7-1. http://CRAN.R-project.org/package=meta) were used for all statistical analyses.

Results

Studies selection

From 1,079 abstracts, we selected 108 full-text articles that were assessed for eligibility. After evaluating the full-text articles, 8 fitted our selection criteria and were finally selected for the systematic review and meta-analysis [8-15]. Studies overview is summarized in Table 1. An outline of the systematic review process is depicted in Figure 1. A Cohen k statistic of 90% was obtained for the final selection process.

A total of 7 European national TAVI registries (Belgium, France, Germany, Italy, Spain, Swiss, UK) were identified including a total of 9786 patients who received TF SAPIEN (n=2885), TA SAPIEN (n=2252) and Core Valve (n=4649) implantation. All but Italian and Swiss registries reported on the three technologies. Two different Italian TAVI registries reported on TA SAPIEN and Core Valve implantation separately. The Swiss registry reported on TF SAPIEN and Core Valve only. Average logistic EuroSCORE ranged from 16% (Spain registry, Core Valve group) to 33% (Belgian registry, TA SAPIEN group).

30-day mortality

Pooled estimate for the incidence of 30-day mortality (Figure 2) was 0.08 [95%CI: 0.05-0.11], 0.12 [95%CI: 0.07-0.19] and 0.06 [95%CI: 0.03-0.11] for TF SAPIEN™, TA SAPIEN and Core Valve respectively (test for subgroup difference P = 0.18). High heterogeneity among registries was found for TF SAPIEN (I^2 = 86.6%), TA SAPIEN (I^2 = 93.3%) and Core Valve (I^2 = 97%) technologies. No publication bias was detected (P = 0.31). Multivariate meta-regression found that TA SAPIEN technology (b coefficient 0.60; P = 0.001) and number of centres involved (b coefficient 0.14; P = 0.03) were independently associated with an increased risk of 30-day mortality. On the other hand, TAVI performed in Spain (b coefficient -4.3; P = 0.03), in Italy (b coefficient -2.1; P < 0.0001), in UK (b coefficient -1.95; P = 0.01) and in France (b coefficient -2.8; P = 0.03) were associated with a lower 30-day mortality. Patients risk profile assessed by the average Logistic EuroSCORE was not associated with 30-day mortality (P = 0.9). Moderators included in the multivariate model accounted for 98% amount of heterogeneity with no significant residual heterogeneity (P = 0.25).

Stroke

Pooled estimate for the incidence of stroke (Figure 3) was 0.03 [95%CI: 0.03-0.04], 0.03 [95%CI: 0.02-0.05] and 0.03 [0.02-0.04] for TF SAPIEN™, TA SAPIEN and Core Valve respectively (test for subgroup difference P = 0.79). High heterogeneity was found among registries for TA SAPIEN (I^2 = 81.2%) whilst TF SAPIEN and Core Valve were associated with low heterogeneity for stroke incidence (I^2=0% and I^2=32.6% respectively). No publication bias was detected (P = 0.27). Multivariate meta-regression found that procedures performed in Italy only were independently associated with a lower incidence of stroke (b coefficient -1.5; P = 0.02). Patients risk profile assessed by the average Logistic EuroSCORE was not associated with the incidence of stroke (P = 0.74). Moderators included in the multivariate model accounted for 82.4% amount of heterogeneity with no significant residual heterogeneity (P = 0.32).

Need for pacemaker implantation

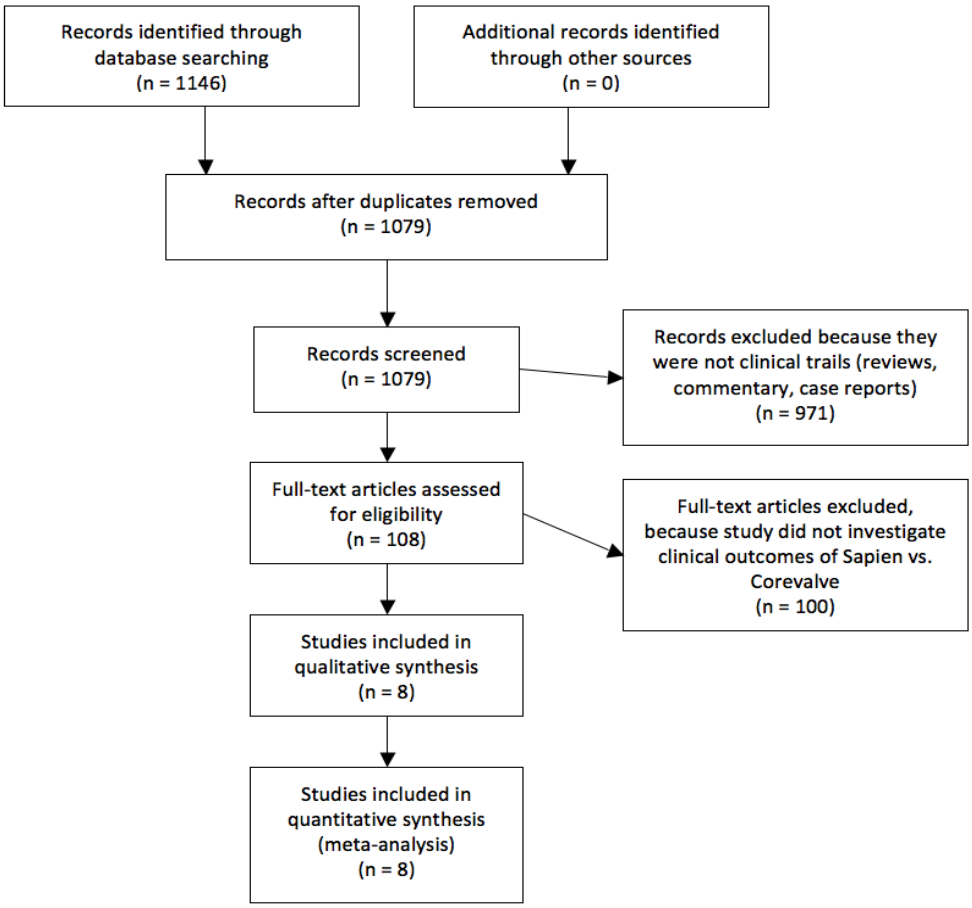
Pooled estimate for incidence of pacemaker implantation (Figure 4) was 0.08 [95%CI: 0.05-0.11], 0.07 [95%CI: 0.04-0.11] and 0.22 [95%CI: 0.19-0.26] for TF SAPIEN™, TA SAPIEN and Core Valve respectively (test for subgroup difference P < 0.0001). High heterogeneity was found among registries for TF SAPIEN (I^2 = 80.9%), TA SAPIEN (I^2 = 88.8%) and Core Valve (I^2 = 83%) technologies. No publication bias was detected (P = 0.08). Multivariate meta-regression found that TF SAPIEN (b coefficient -1.2; P < 0.0001) and TA SAPIEN (b coefficient -1.08; P = 0.001) were independently associated with a lower risk of pacemaker implantation.

Table 1: Registries overview

Registry (1)	Period	N	TAVI technology	n	Logistic Euro SCORE
Belgian National TAVI Registry [8].	2007-2010	15	SAPIEN TF	99	29
			SAPIEN TA	88	33
			Core Valve	141	25
FRANCE 2 TAVI Registry [9]	2010-2011	34	SAPIEN TF	1540	22.2
			SAPIEN TA	567	24.8
			Core Valve	1043	21.3
German TAVI Registry [10]	2009-2010	22	SAPIEN TF	123	20.3
			SAPIEN TA	113	20.3
			Core Valve	1074	20.3
Italian Registry TA TAVI [11]	2008-2012	21	SAPIEN TA	774	25.6
Italian Multicentre Core Valve Registry [12]	2007-2009	14	Core Valve	659	23
Spain TAVI Registry [13].	2010-2011	44	SAPIEN TF	504	17
			SAPIEN TA	302	19.2
			Core Valve	610	16
SWISS TAVI Registry [14]	2011-2013	8	SAPIEN TF	232	20.2
			Core Valve	324	20.2
UK TAVI Registry [15]	2007-2010	30	SAPIEN TF	387	17.7
			SAPIEN TA	408	22.5
			Core Valve	798	20.25

N= number of participating centres, TAVI = transcatheter aortic valve implantation; n = number of patients, TF = transfemoral; TA = transapical; UK = United Kingdom, (1) = all registries stated being funded by the manufacturer except [8] and [13].

Figure 1. Outline of the systematic review process



Patients risk profile assessed by the average Logistic EuroSCORE was not associated with the rate of pacemaker implantation (P = 0.78). Moderators included in the multivariate model accounted for 90.5% amount of heterogeneity but significant residual heterogeneity was found (P = 0.02).

Aortic paravalvular leak

Pooled estimate for the incidence of aortic paravalvular leak ≥2 (Figure 5) was 0.07 [95%CI: 0.05-0.11], 0.06 [95%CI: 0.05-0.08] and 0.07 [95%CI: 0.04-0.12] for TF SAPIEN™, TA SAPIEN and Core Valve respectively (test for subgroup difference P = 0.9). High heterogeneity was found among registries for TF SAPIEN (I^2 = 84.7%) and Core Valve (I^2 = 94.4%) but not for TA SAPIEN (I^2 = 29.1%) but significant publication bias was detected (P = 0.002). Trim and fill method suggested an overall prevalence of aortic paravalvular leak of 0.10 [95%CI: 0.0767-0.131]

1-year mortality

Pooled estimate for incidence of 1-year mortality (Figure 6) was 0.15 [95% CI: 0.14-0.16], 0.23 [95%CI: 0.19-0.28] and 0.17 [95%CI: 0.15-0.19] for TF SAPIEN™, TA SAPIEN and Core Valve respectively (test for subgroup difference P = 0.0008). High heterogeneity was found among registries for TA SAPIEN (I^2 = 81.9%) and Core Valve (I^2 = 59.3%) but not for TF SAPIEN (I^2 = 0%). No publication bias was detected (P = 0.25). At multivariate meta-regression, Logistic EuroSCORE was moderately associated with 1-year mortality (b coefficient 0.07; P = 0.06,). TAVI technologies did not impact on 1 year mortality (TF SAPIEN versus Core Valve (b coefficient -0.1428; P = 0.07) and TA SAPIEN versus Core Valve (b coefficient 0.1515; P = 0.3). Moderators included in the multivariate model accounted for 100% amount of heterogeneity and no significant residual heterogeneity was found (P = 0.48).

Figure 2: Meta-analysis for proportion of 30-day mortality.

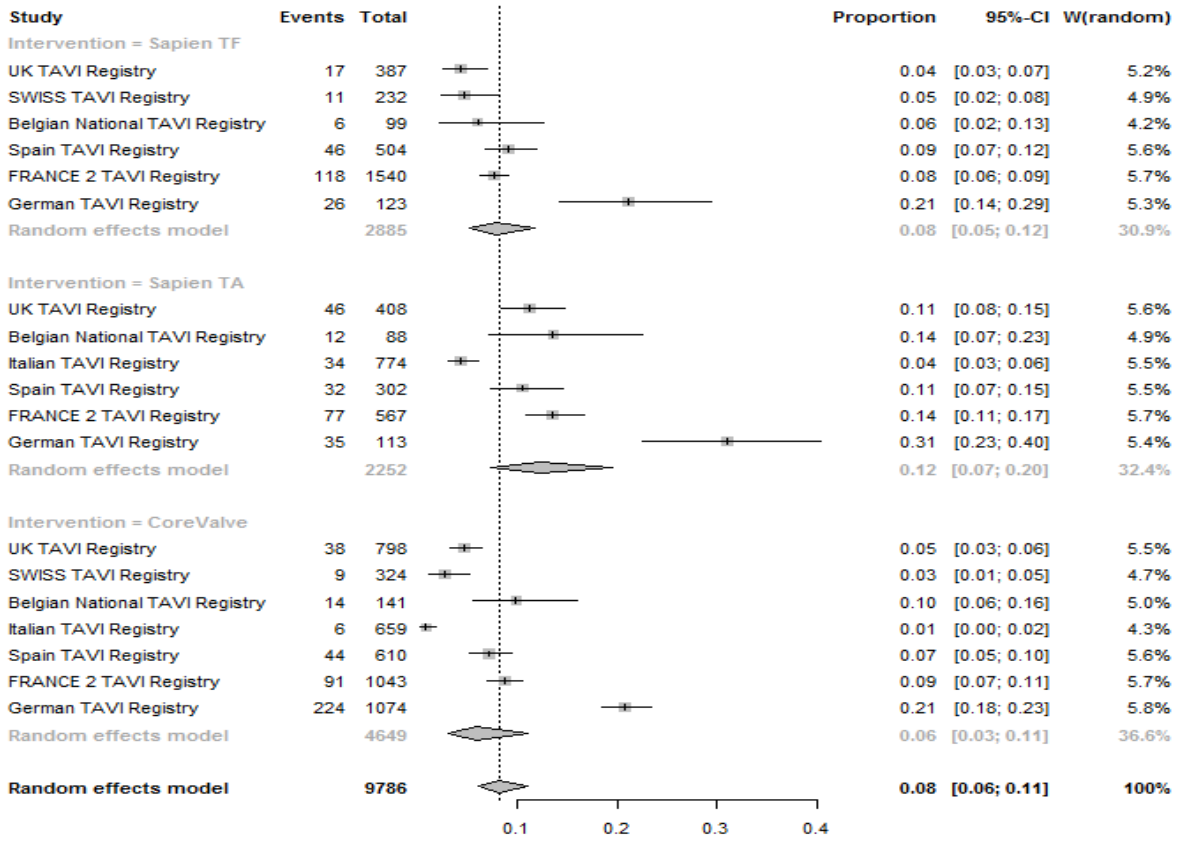


Figure 3. Meta-analysis for proportions of stroke

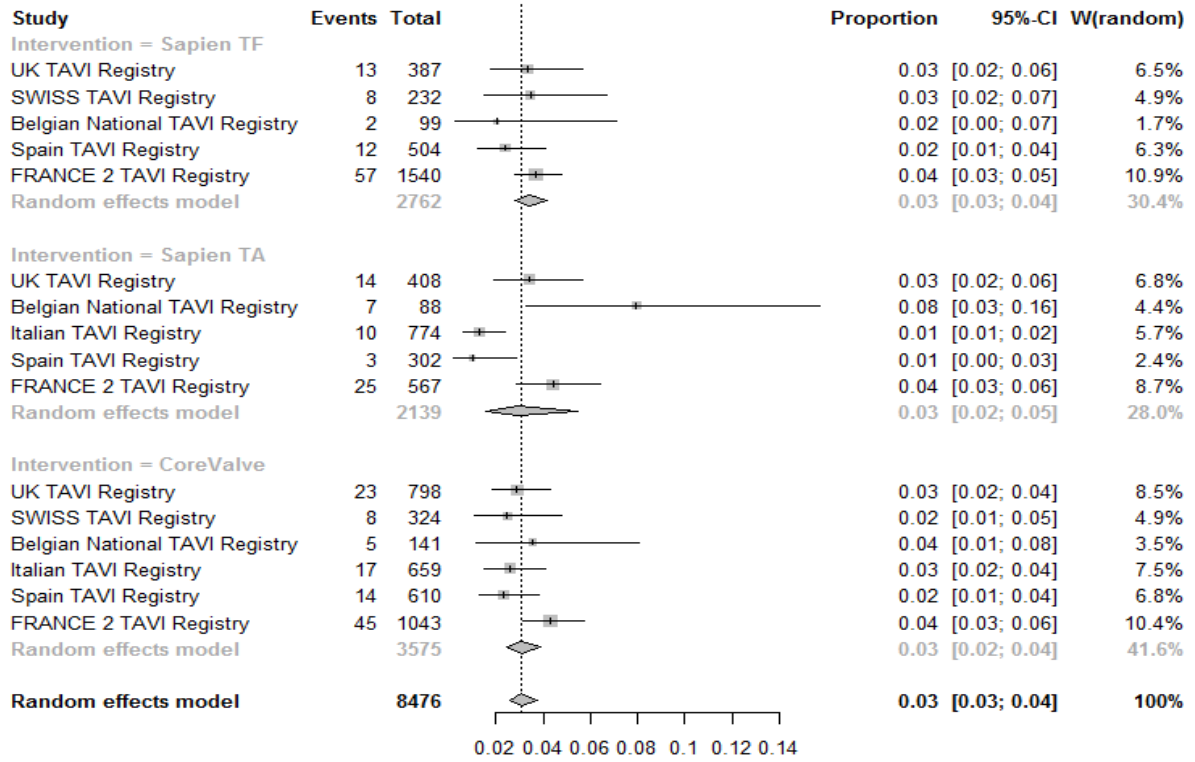


Figure 4. Meta-analysis for proportions of pacemaker requirement

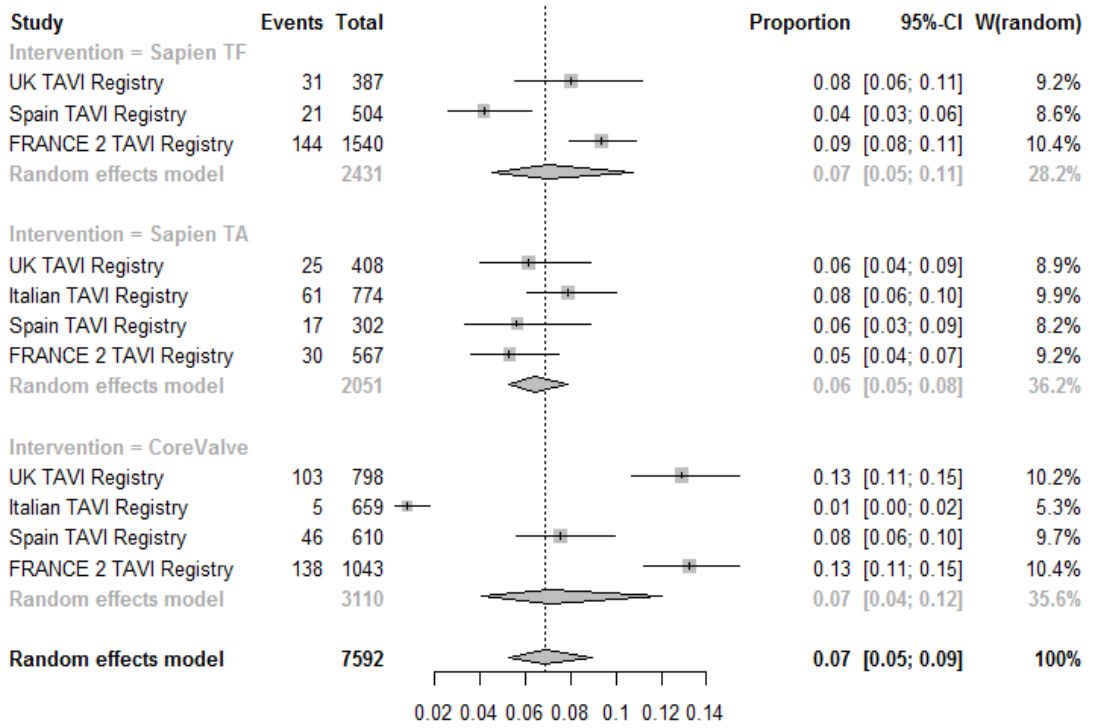


Figure 5. Meta-analysis for proportions of Incidence of paravalvular leak ≥ 2

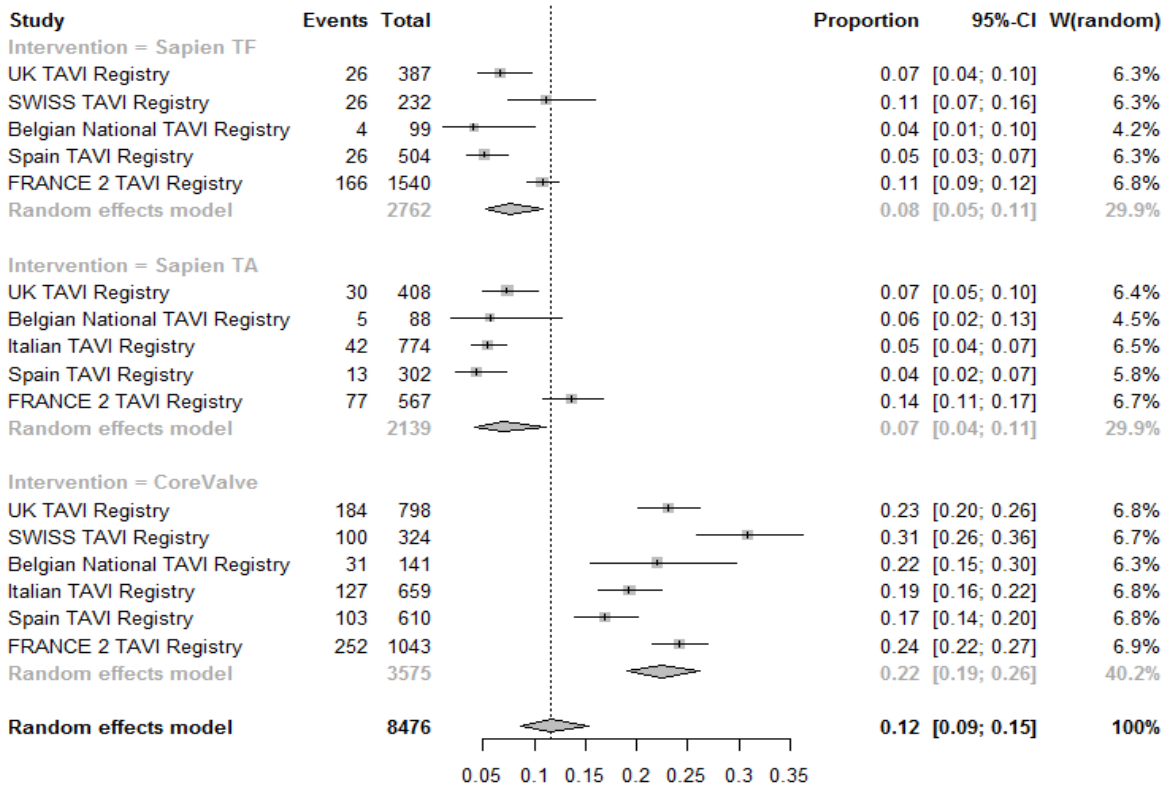
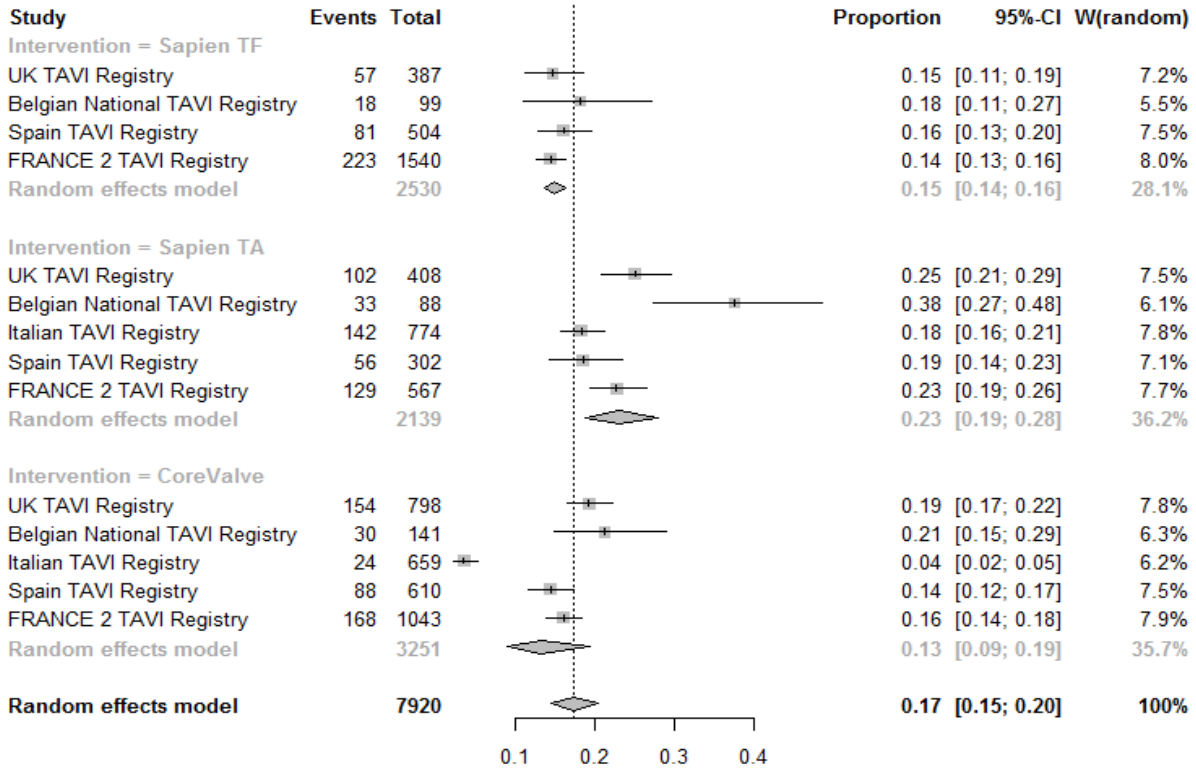


Figure 6. Meta-analysis for proportions of 1-year mortality



Discussion

The main finding of the present study was that in the European real world practice, trans-vascular TAVI approaches were associated with a lower early mortality regardless of the type of device used and did not increase the risk of stroke or significant paravalvular leak. Core Valve technology was associated with > 2 folds increased risk for pacemaker implantation. There was a marked heterogeneity among European countries for all short-term outcomes investigated and we found an association between 30-day mortality and European country where the procedure was performed. Of note Logistic Euro SCORE which is widely adopted in Europe to discriminate high-risk patients suitable for TAVI, failed to predict early mortality (within 30 days) but it presented a moderate association with 1-year mortality. Despite crude 1 year mortality was higher among patients receiving TA SAPIEN technology, this effect was no longer present when adjusted for patients' risk profile.

Based on the compelling evidence of the randomized Placement of Aortic Transcatheter Valves (PARTNER) A and B cohort [2,3], TAVI is now considered standard of care for extreme risk and inoperable patients in Europe and is an alternative to surgery for high-risk patients with symptomatic aortic stenosis [4]. However, the major drawback of PARTNER is the highly selected study cohort that does not reflect the daily clinical practice. TAVI registries represent a real-world scenario, and therefore might provide the evidence for the treatment of high-risk patients. In the PARTNER trial A, 30-day mortality was 3.4% and 6.5% for TF TAVI and surgical aortic valve replacement respectively. In PARTNER trial B, 30-day mortality was 5% after TAVI. In the STACCATO trial [16], 30-day mortality was 5.8% in TA SAPIEN TAVI group. The present analysis showed that in the real European clinical practice 30-day mortality for TAVI (8%) is higher than that observed in randomized trials particularly after TA approach (12%) and this reflects the higher risk profile of unselected patients in the daily practice. Interestingly, the mortality rate in the TA cohort is not consistent with a number of published series [17,18], which deserves careful

examination in order to identify the reasons for this discrepancy.

Despite we attempted to adjust the effect of TAVI technologies on early mortality for patients risk profile using logistic Euro SCORE, a substantial selection bias resulting from the inclusion of patients with a higher co-morbidity rate (mainly peripheral disease) in the TA SAPIEN group might partially explain the higher risk of early mortality observed. Of note, logistic Euro SCORE was not associated with 30-day mortality in the present analysis. It is widely recognized that the logistic Euro SCORE is not an ideal tool for measuring the pre procedural risk of TAVI, as the predicted mortality is grossly overestimated [19].

The present analysis found that early mortality after TAVI varied significantly across European countries regardless of the type of technology used and the patients risk profile according to the logistic Euro SCORE. These discrepancies might be partially explained by different policies in patient selection and patient risk profile not accounted for by the logistic Euro SCORE. However, heterogeneity in early mortality across European countries highlights the urgent need for standardized criteria for patient selection.

The incidence of stroke after TAVI in the PARTENR A, PARTNER B and the STACCATO trials was 5.5%, 6.7% and 8.8% respectively. In the European real-world clinical practice the incidence of stroke at ≤ 30 days was relatively low 3.0% without any difference among TAVI technologies. This result is particularly encouraging considering the risk of perioperative stroke following surgical AVR in elderly patients ranges from 3 to 7%. [20] Careful patient selection, device preparation, optimal device progression, and positioning, as well as adequate anti-platelet pre-medication and anticoagulation regimen are likely to reduce this risk.

This analysis confirmed that Core Valve technology is associated with an increased rate of pacemaker implantation than SAPIEN technologies (8%). However, the rate of pacemaker implantation in patients receiving SAPIEN technologies was higher than those reported in the PARTNET trial A (3.8%) and B (3.4%) and probably this aspect reflect an increased anatomic complexity for TAVI in the real-world practice.

The incidence of paravalvular leak ≥ 2 was 7% across European countries and this result is better than that reported in PARTNER A (12.2%) and B (11.8%) trials. This result seems to be encouraging due to the potential detrimental effect of post procedural paravalvular leak on outcomes [21]. However, the absence of standardized definition and protocols to detect (i.e. angiography versus echocardiography) and score (qualitative or semi quantitative methods) the incidence of leak limits definitive conclusion. Moreover, the present analysis did not confirm the protective effect of the SAPIEN valve against post-procedural moderate to severe aortic regurgitation previously described although this information was omitted in some registries.

Finally, in the European real-world clinical practice, one-year survival seems more “patient-related” rather than “procedure-related.” Of note, despite the logistic Euro SCORE was unable to predict early mortality, it was the only moderator marginally associated with 1 year mortality across European national registries.

In conclusion, in the European real world practice TAVI is associated with a higher mortality than that reported in randomized trials. This result is mainly related with the higher risk profile of non-selected patients currently referred for TAVI. However, according to the results of this meta-analysis, TA TAVI results are still unsatisfactory and trans vascular TAVI should be considered as the first line approach. Our analysis confirms that the only real difference in outcomes between the 2 trans vascular devices is the requirement for permanent pacemaker. The significant heterogeneity in early mortality across European countries suggests the urgent need for standardization of patient selection process and procedural aspects in order to optimise outcomes, resource consumption and to guarantee high standards of care across European countries. Despite the fact that in Europe patients are currently selected for TAVI on the basis of their surgical risk measured by the

logistic Euro SCORE (≥20%), such a risk stratification system is ineffective in predicting early mortality after TAVI in daily clinical practice. Therefore, there is also an urgent need to develop a TAVI risk score for patient selection. European TAVI registries might provide powered sample sized TAVI populations to be used to generate a "tailored" TAVI risk score. However, to collect data on such large numbers of patients it will be necessary to standardize definitions and clinical end points after TAVI.

Conflicts of Interest: None.

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