Simultaneous versus staged approach in transcatheter aortic valve implantation for severe stenosis and endovascular aortic repair for thoracic and abdominal aortic aneurysm.

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ABSTRACT

OBJECTIVES

Thoracic/abdominal aortic aneurysms(T/AAAs) and aortic stenosis(AS) may be concomitant diseases requiring both transcatheter aortic valve implantation(TAVI) and endovascular aneurysm repair(T/EVAR) in high risk patients for surgical approaches, but temporal management is not clearly defined, yet. Aim of the study was to analyze outcomes of simultaneous vs staged TAVI and T/EVAR.

METHODS

Retrospective observational multicenter study on patients requiring TAVI and T/EVAR from 2016 to 2022. Patients were divided into 2 groups: "Simultaneous group" if T/EVAR+TAVI were performed in the same procedure and "Staged group" if T/EVAR and TAVI were performed in two steps, but within 3 months. Primary outcomes were: technical success, 30-day mortality/major adverse events and follow-up survival. Secondary outcomes were procedural metrics and length of stay (LOS).

RESULTS

Forty-four cases were collected; 8(18%) had TEVAR and 36(82%) EVAR, respectively. Upon temporal determination 25(57%) and 19(43%) were clustered in simultaneous and staged groups,, respectively. In staged group, median time between procedures was 72(inter-quartile-range–IQR:57-87) days. Preoperative and intraoperative figures were similar. There was no difference in 30-day mortality(Simultanoeus:0/25 vs Staged:1/19;p=.43). Pulmonary events(Simultaneous:0/25 vs Staged:5/19;p=.01) and need of postoperative cardiac pacemaker(Simultaneous:2/25 vs Staged:7/19;p=.02) were more frequent in Staged patients. The overall LOS was lower in Simultaneous group[Simultaneous:7(IQR:6-8) vs Staged:19(IQR:15-23)days;p=.001]. The median

follow-up was 25(IQR:8-42) months and estimated 3-year survival was 73% with no difference between groups(Simultanoeus:82% vs Staged:74%;p=.90).

CONCLUSION

Both simultaneous or staged T/EVAR and TAVI procedures are effective with satisfactory outcomes. Despite the small numbers, simultaneous repair seems to reduce length-of-stay and pulmonary complications, maintaining similar follow-up survival.

KEYWORDS: transcatheter aortic valve implantation; endovascular aortic repair; abdominal aortic aneurysm; TAVI; EVAR, TEVAR.

ABBREVIATIONS AND ACRONYMS

TAAA: Thoracic Abdominal Aortic Aneurysm

AAA: Abdominal Aortic Aneurysm

TAVI: Transcatheter Aortic Valve Implantation

LOS: Length of Stay

TEVAR: Thoracic Endovascular Aortic Repair

EVAR: Endovascular Aortic Repair

AS: Aortic Valve Stenosis

TF: Trans Femoral

CTA: Computed tomography angiography

VARC: Valve Academic Research Consortium

IQR: Interquartile range

SAVR: Surgical Aortic Valve Replacement

INTRODUCTION

According to the current international guidelines, transcatheter aortic valve implantation (TAVI) is the recommended option for treating patients with symptomatic and severe aortic valve stenosis (AS) in older patients (>_75 years) and at high-risk or anatomically unsuitable for surgical aortic valve repair (SAVR). Trans-femoral (TF) approach is an available option with reduced perioperative morbidity and mortality when compared to trans-axillary, trans-aortic, and trans-apical routes[1–3]

The presence of concomitant aortic-iliac arterial diseases or vascular access complications during TF-TAVI may reduce the benefits of this approach, as they are associated with prolonged hospitalization, and post-operative increased mortality rates[4,5] Concomitant AS and thoracic or abdominal aortic aneurysms (TAAs/AAAs) is not uncommon [6], but no clear recommendations are reported into guidelines[1,7,8] and their ideal temporal management is yet to be defined, since only anecdotal data are available about concomitant endovascular aneurysm repair (T/EVAR) and TF-TAVI[9]. From an hypothetical standpoint, a simultaneous repair may benefit exposing the patient to a single procedure, however issues might be considered in combining two main interventions in the same setting. Therefore aim of the study was to report the results of the endovascular management of concomitant severe AS and TAAs or AAAs both in simultaneous and staged approach.

METHODS

Study design/patient selections.

It was an retrospective observational, nationwide study focused on patients with concomitant severe and symptomatic AS and presenting with symptomatic/asymptomatic TAAs or AAAs, undergoing TF-TAVI and T/EVAR, between 2016 and 2022.

Patients were divided into 2 groups:

- Simultaneous group: T/EVAR+TF-TAVI in the same procedure
- Staged group: T/EVAR and TF-TAVI performed within 3 months.

Data from simultaneous and staged groups were compared for the study's outcomes.

Data Availability Statement

Data were retrospectively collected in each center from clinical records, shared anonymously and analyzed. Due to its retrospective nature, individual informed consent was waived and Institutional review Board was obtained in accordance with the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) guidelines for the observational studies[10]. All relevant data are within the manuscript and its Supporting Information files.

Preoperative work-up.

Patients were evaluated for an aortic valve replacement in case of severe and symptomatic AS, confirmed by a transthoracic echocardiography (mean gradient > 40 mmHg or aortic valve area <1.0 cm^2)[1]. A multidisciplinary Heart Team, composed by Cardiologists, Interventional Cardiologists, Cardiac Anesthetists and Cardiac Surgeons, was involved in the patient selection and older patients (≥75 years) or high surgical risk for surgical aortic valve replacement (SAVR) were considered for TAVI[1]. An ECG-gated cardiac and thoracoabdominal computed tomography angiography (CTA) was evaluated for the valve-graft sizing and femoral/iliac or axillary access analysis. Patients were included in the study only if TAVI procedure was performed by transfemoral approach. In case of any vascular issue, an adjunctive preoperative consultation by Vascular Surgeons was performed. Indication for T/EVAR was considered by Vascular Surgeon according to the current guidelines [7,8]. Patients were decided to undergo prior T/EVAR or TAVI or do both interventions in the same procedures, based on specific patients fitness, urgency of the repair per each pathology and institutional protocols. Patients with staged procedures with interval time

longer than 3 months were arbitrary excluded from the study in order to reduce confounding factor in this specific fragile population that may interfere with the specific outcomes of the procedures. Aiming to analyze procedural outcomes, patients that did not perform both procedure due to clinical or other issues were excluded from the study.

Definitions and outcomes.

Technical success, 30-day mortality/major-adverse-events(MAEs) and follow-up survival were assessed as primary outcomes. Procedure/fluoroscopy time, contrast media volume and hospitalization were evaluated as secondary outcomes. The cumulative data/events from both procedures for Staged group were taken into account when comparing with Simultaneous group.

Technical success was defined as the combination of successful deployment of the cardiac valve according to the VARC (Valve Academic Research Consortium) 3 definition and aortic endograft[11].

30-day mortality and MAEs were classified as by reporting standards [11]. Vascular complications were defined and classified according to the VARC 3 guidelines[12].

Statistical analysis. Continuous data were reported as a median and interquartile range (IQR). Categorical data were expressed as frequency. Differences between Simultaneous vs Staged groups were evaluated by Fisher's exact test and Mann-Whitney test for categorical and continuous variables. Follow-up survival analysis was estimated by Kaplan-Meier analysis and difference between Simultaneous vs Staged groups was evaluated by Log-Rank. Univariate analysis were performed and logistic regression multivariate analysis models were used to adjust for confounders. P value was considered significant when it was < 0.05. Statistical analysis was performed by SPSS 28.0 (SPSS Inc., Chicago, IL, USA).

RESULTS

Patients selection. Forty-four patients required concomitant or early deferred aortic aneurysm repair and TF-TAVI: 8(18%) had a TAA and 36(82%) an AAA, respectively. The median age and aneurysm diameter were 82(IQR:73-87) years and 58(IQR:50-71) mm, respectively. Three (7%) patients had a symptomatic aneurysm with abdominal pain and were treated by standard endovascular infrarenal repair first followed by staged TF-TAVI, 5(11%) had acute heart failure at the moment of the hospitalization and 14(32%) a history of acute heart failure within 3 preprocedural months. 25(57%) and 19(43%) cases were grouped in Simultaneous and Staged groups, respectively. Demographics and pre-operative data are reported in Table 1 and they were similar in the two groups, except for female gender (p=.001), more frequent in the Simultaneous group.

Procedure. Table 2 summarizes the major procedural details. The median time between the T/EVAR and TAVI procedures in the Staged group was 72(IQR:57-87) days. Technical success (T/EVAR+TF-TAVI) was achieved in all cases. Details of the endograft used for T/EVAR procedures and type of valves used for TAVI are summarized in Supplementary Table 1.

Early results. Table 3 summarizes adverse events within 30 post-operative days.

Pulmonary adverse events (Simultaneous:0/25 vs Staged:5/19 vs;p =.01) and need of postoperative cardiac pacemaker (Simultaneous:2/25 vs Staged:7/19;p =.02) were more frequent in the staged group. One(2%) patient died within 30 days(Simultaneous:0/25 vs Staged:1/19;p =.43): an 84 years-old male who underwent EVAR first and TF-TAVI after 86 days; the second postoperative course was

complicated by urinary sepsis causing final exitus. The overall hospitalization was higher in Staged group than Simultaneous one (Simultaneous:7(IQR:6-8) vs Staged:19(IQR:15-23)days;p=.001).

Subgroups analysis.

The aneurysm repair was performed before TF-TAVI in 18/25(72%) cases in Simultaneous group and in 9/19(47%) in Staged group, performing prior T/EVAR either prior TAVI (Table 4).

Overall, 36(82%) of patients received a EVAR and 8(18%) a TEVAR procedure for infrarenal or thoracic aortic pathology, respectively (Table 5).

Follow-up results. The median follow-up was 25(IQR:8-42) months. Estimated 3-year survival was 73% at Kaplan-Maier analysis, with no difference between groups (Simultaneous:82% vs Staged:74%;LogRank-p=.90;figure1). Causes of mortality in Supplementary Table 2. There was no difference in re-hospitalization (Simultaneous:5/25 vs Staged:4/19;p=.30) and procedure related reinterventions (Simultaneous:1/25 vs Staged:2/19;p=1). Causes of re-hospitalization and reinterventions are reported in Supplementary Table 3. Two patients underwent reintervention due to iliac recoil after stenting and femoral pseudoaneurysm after percutaneous access.

Univariate and Multivariate analysis.

Among primary endpoints, staged repair appeared to be a risk factor for pulmonary adverse events (OddRatio[OR]=7.4;95%ConfidenceInterval[95%CI]=3.4-7.6;p=.006). Multivariate analysis adjusted for potential confounders, confirmed the independent role of the staged procedure (OR=15.2;95%CI=5.4-8.9;p=<.001). Follow-up survival was not impacted by staged vs simultaneous approach. The need for permanent cardiac pacemaker was the unique independent factor for follow-up mortality (Hazard Ratio=6.3;95%CI=3.4-7.6;P=.012).

DISCUSSION

In the present manuscript we report 44 patients with concomitant severe AS and T/AAAs, gathered from a multicenter nationwide experience within 7 years. Overall results were satisfactory in terms of technical success, early clinical results and a low number of vascular access complications. Follow-up mortality were also encouraging, especially if we consider high-surgical risk patients.

Concomitant AS and T/AAAs is not uncommon nowadays because the increasing age of population as well as multiple aortic comorbidities. [1,7,13]. Up today, there are no definitive recommendations about the concomitant management of these diseases[1,7,8,13].

Historically, in low risk patients, the gold standard approach is by a surgical aortic valve replacement (SAVR) first performed by cardiac surgeons followed by aneurysm repair[1,9]. However, SAVR is usually associated with postoperative increase of systolic blood pressure and risk of aneurysm rupture[14]. On the other hand, issues arise when performing an aneurysm repair as first step, due to severe fluctuation of blood pressure during aortic clamping[15].

In the last decades, the endovascular revolutions in both cardiac and vascular surgery allowed to guarantee mini-invasive solutions with effective and reproducible outcomes both for AS and T/AAAs[1,7]. For these reasons, the current management of concomitant symptomatic and severe AS and T/AAAs is changing, and simultaneous endovascular repair could be feasible.

The first report of simultaneous TF-TAVI and EVAR was managed by Smith et al. in 2012[16]. Table 6 provides a summary of the 25 cases reported in the literature about simultaneous TF-TAVI and EVAR procedures. Bramucci et al[13] reported in 2023 the first case of simultaneous TF-TAVI and EVAR performed by total percutaneous approach, under local anesthesia.

In the present series we have reported a wide series on this topic and compared cases treated in a single simultaneous procedure with cases managed by staged strategy. Preoperative

clinical features were comparable between 2 groups, except for female gender, more frequent in simultaneous group.[17]

Even if concomitant TF-TAVI and T/EVAR may increase the complexity of a single procedure, our series demonstrates no differences in intraoperative figures as well as in postoperative mortality between groups. Specifically, postoperative pulmonary adverse events, the need of permanent cardiac pacemaker and length-of-stay resulted higher in the staged group. We might speculate to address these findings with the need of multiple hospitalizations, especially in such a fragile population. Moreover as resulted in the multivariate analysis as collateral finding, the permanent cardiac pacemaker was linked to a reduction in survival during follow-up.

Post operative AKI is one of the most frequent complications after both T/EVAR and TAVI [18]. Tailored preoperative planning, automated CO_2 angiography[19] and IVUS play a crucial role in the reduction of renal toxicity guaranteeing non necessity of post-operative hemodialysis.

Follow-up results are currently lacking in literature because there are only few preliminary reports describing the feasibility/effectiveness[9,13,15,20,21]. In the present series follow-up mortality is not negligible, but acceptable in consideration of the fragile patients' population.

However, there are still open questions about timing/management even in case of concomitant TF-TAVI and T/EVAR. In the present series numbers are too small to find any statistical association between preoperative morphological/clinical features and different timing of repair. Moreover, the retrospective and multicenter cases enrollment plays a role in the heterogeneity of these different approaches and since every multidisciplinary team based decision on the on specific patients fitness, urgency of the repair per-each pathology and institutional protocols, no clear data on the indications are specified in this study, focusing on the procedural aspects. Future researches should better investigate specific morphological/clinical factors that may benefit for a staged or simultaneous approach, given the favorable results from this first experience.

The present study has several design limits. It is a retrospective analysis, with small sample size and limited follow-up, with few events ranging from 0 to 5, so type 2 statical error is to be taken into account and complex statistical consideration should be considered in light of this.

Eventually, the retrospective design and the inclusion criteria that were specifically considered just on patient that underwent both procedures, lead us to have no data about patients managed by staged approach, but unable to complete due to inter-procedural complications mortality.

The main advantage of a concomitant endovascular treatment of both AS and T/AAAs consists of using the same access for both procedures: both EVAR and TAVI require large femoral bore and a combination of both procedures may reduce the risk of vascular access complications, as suggested by the low numbers reported in our cohort, thanks to active hostile iliac vessels preparation[3]. Moreover, it allows to solve in a single procedure 2 different serious illness, avoiding any risk of mortality between therapeutic steps. At the same time the combined procedure allows to face directly serious related complications: 1) the hemodynamic issues that might be relevant during aortic repair and may be highlighted due to the severe AS; 2) the risk for aortic rupture or dissection that can arise while navigating TAVI in an aneurysmatic aorta that may suggest to use an alternative approach such as transapical or axillary ones, none presented in our series of 100% TF-TAVI. 3) Eventually, a simultaneous approach may also reduce the overall periprocedural costs due to a reduced pulmonary complication rate and shorter hospitalization period.

CONCLUSIONS

Simultaneous or staged thoracic/abdominal endovascular aortic repair and TAVI are effective with satisfactory outcomes with both strategies. Despite small numbers, simultaneous endovascular repair seem to offers significant reduction of overall hospitalization and pulmonary complications,

yet maintaining similar procedure-related follow-up outcomes. These data may be considered in the implementation of multidisciplinary teams of with Cardiac, Vascular Surgeons and Interventional Cardiologists while evaluating high surgical risk patients presenting both pathologies.

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Figure legend.

Figure 1. A) Estimated overall survival by Kaplan Meier analysis. **B)** Estimated survival by Kaplan Meier analysis in patients managed by simultaneous and staged approaches.

Graphical Abstract: Summary of the study design (left panel) and the main results and outcomes (right panel)

TABLES

Table 1. Demographics and preoperative risk-factors.

	Overall - 44 N(%)	**Simultaneous** - 25 N(%)	**Staged -** 19 N(%)	**P**
Male	30(68)	13(52)	17(89)	.01
Body mass index > 31	8(18)	5(20)	3(18)	.27
Hypertension	41(93)	24(96)	17(89)	.57
Dyslipidemia	40(91)	22(88)	18(95)	.62
Active smoker	9(20)	5(20)	4(21)	.53
History of smoke	22(50)	11(44)	11(57)	.28
Diabetes	9(21)	5(20)	4(21)	1
Chronic obstructive pulmonary disease	15(34)	8(32)	7(36)	.75
Coronary artery disease	27(61)	13(52)	14(74)	.21
Atrial fibrillation	10(23)	6(24)	4(21)	.47
Cerebral vascular insufficiency	7(16)	3(12)	4(21)	.21
Peripheral arterial occlusive disease	8(18)	5(20)	3(16)	1.0
Chronic Renal failure	20(45)	12(48)	8(42)	.13
Dialysis	0(0)	0(0)	0(0)	-
History of heart failure (within 3 months)	14(32)	9(36)	5(26)	.60
Active heart failure	5(11)	3(12)	2(12)	1
Medical therapy				

Dual antiplatelet	13(30)	6(24)	7(36)	.57
Anticoagulant therapy	13(30)	8(32)	5(26)	.74
Statin	42(96)	23(92)	19(100)	.49
Previous infrarenal aortic repair	7(16)	3(12)	4(21)	.44
Surgical	3(7)	1(4)	2(12)	.60
Endovascular	5(11)	2(8)	3(18)	.63
American Score of Anesthesiologist				
3	14(32)	6(24)	8(42)	.32
4	30(68)	19(76)	11(57)	.33
Hostile bilateral femoral / iliac access	11(25)	6(24)	5(26)	.89
	Median(IQR)	Median(IQR)	Median(IQR)	
Age (years)	82(78-86)	81(76-86)	83(79 - 87)	.32
Preoperative creatinine (mg/dL)	1.3(0.9-1.7)	1.2(1.0-1.4)	1.3(1.1-1.5)	.43
Preoperative eGFR (mL/min)	59(45-73)	59(44-73)	58(45-71)	.23
Aneurysm diameter (mm)	58(55-61)	57(55-59)	61(57-65)	.07

N= Numbers

Table 2. Procedural details

	Overall - 44 N(%)	**Simultaneous** - 25 N(%)	**Staged** - 19 N(%)	**P**
Anesthesia for TEVAR/EVAR				
Local	16(34)	9(36)	7(37)	1
Loco-regional	5(11)	2(8)	3(16)	.63
General	23(52)	14(56)	9(47)	.76
Femoral access TEVAR EVAR				
Percutaneous	27(61)	16(64)	11(58)	.76
Surgical cut down	17(39)	9(36)	8(42)	.92
Femoral access TAVI				
Percutaneous	30(68)	16(64)	14(74)	.28
Surgical cut down	14(32)	9(36)	5(26)	.63
Aortic endograft configuration				
Tube	7(16)	3(12)	4(21)	.44
Aortic–bi-iliac	37(84)	22(88)	15(79)	.44
Iliac artery balloon angioplasty	2(5)	1(4)	1(5)	1
Iliac artery stenting	2(5)	1(4)	1(5)	1
Hypogastric artery embolization	2(5)	0(0)	2(11)	.10
Blood transfusion	12(27)	9(36)	3(16)	.18
Technical success	44(100)	25(100)	19(100)	1

Type II endoleak	2(5)	1(4)	1(5)	1
	Median(IQR)	Median(IQR)	Median(IQR)	
Size of main access for T/EVAR (Fr)	18(16-20)	18(16-20)	18(16-20)	1
Size of main access for TAVI (Fr)	14(13-15)	14(12–16)	14(12-16)	1
Procedural time (min)	181(163-199)	175(156-194)	190(179-201)	.87
Fluoroscopy time (min)	38(32-446)	40(36-44)	42(39-45)	.90
Contrast media volume (mL)	203(181-223)	202(166-238)	205(187-223)	.20

N= Numbers Fr: French.

Table 3. Adverse events within 30 post-operative days

	Overall-44 N(%)	**Simultaneous-** 5 N(%)	**Staged**-19 N(%)	**P**
Cardiac adverse events	2(5)	0(0)	2(11)	.18
Cerebrovascular adverse events	2(5)	1(4)	1(5)	1
Gastrointestinal adverse events	0(0)	0(0)	0(0)	-
Renal function worsening Dialysis	5(11) 0	2(8) 0	3(16) 0	.64 -
Pulmonary adverse events	5(11)	0(0)	5(26)	.01
Need of postoperative cardiac pacemaker	9(21)	2(8)	7(37)	.02
Reinterventions	1(2)	0(0)	1(5)	.43
Vascular access complication	2(5)	1(4)	1(5)	1
Death	1(2)	0(0)	1(5)	.43

N= Numbers. Among the 5 cases of renal function worsening reported at 24 postoperative days, 2 returned to baseline value within 30-day.

Table 4. Details of the procedures for both Simultaneous and Staged group.

	Overall-44 N(%)	**Simultaneous Group**			**Staged Group**		
		Overall-25 N(%)	**EVAR first-18 N(%)**	**TAVI first-7 N(%)**	**Overall-19 N(%)**	**EVAR first-10 N(%)**	**TAVI first–9 N(%)**
Preoperative factors							
Male	30(68)	13(52)	7(39)	5(71)	17(89)	9(90)	8(89)
Urgent aneurysm	3(7)	0(0)	0(0)	0(0)	3(16)	3(30)	0(0)
Hostile bilateral femoral / iliac access	11(25)	5(20)	4(22)	1(14)	6(32)	3(30)	3(33)
TEVAR	8(57)	3(12)	3(17)	0(0)	5(26)	2(20)	3(33)
EVAR	36(43)	22(88)	15(83)	7(100)	14(74)	8(80)	6(67)
Days between procedures (Staged group)					72(IQR:57-87)	82 (IQR:32-86)	65(IQR:28-88)
Intraoperative details							
General Anesthesia TEVAR/EVAR	23(52)	14(56)	13(72)	1(14)	9(47)	3(30)	6(67)
Percutaneous femoral access TEVAR/EVAR	27(61)	16(64)	10(56)	6(86)	11(58)	4(40)	7(78)
Percutaneous femoral access TAVI	30(68)	16(64)	10(56)	6(86)	14(74)	7(70)	7(78)

Need for iliac adjunctive procedures	4(9)	1(4)	0(0)	1(14)	3(16)	2(20)	1(11)
Technical Success	44(100)	25(100)	18(100)	7(100)	19(100)	10(100)	9(100)
Post-operative results							
Cardiac adverse events	2(5)	0(0)	0(0)	0(0)	2(11)	1(10)	1(11)
Cerebrovascular adverse events	2(5)	1(4)	0(0)	1(14)	1(5)	0(0)	1(11)
Respiratory adverse events	5(11)	0(0)	0(0)	0(0)	5(26)	2(20)	3(33)
Reinterventions	1(2)	0(0)	0(0)	0(0)	1(5)	1(10)	0(0)
Vascular access complication	2(5)	1(4)	1(6)	0(0)	1(5)	0(0)	1(11)
Death	1(2)	0(0)	0(0)	0(0)	1(5)	1(10)	0(0)

N= Numbers

Table 5. Details of the procedures divided upon aortic repair both as endovascular aortic repair for infrarenal abdominal aorta (EVAR) and thoracic endovascular aortic repair (TEVAR)

	Overall-44 N(%)	**EVAR-36** N(%)	**TEVAR-8** N(%)
Preoperative factors			
Male	30(68)	25(69)	5(62)
Urgent aneurysm	3(7)	3(8)	0(0)
Hostile bilateral femoral / iliac access	11(25)	10(27)	1(12)
Iliac aneurysm	3(7)	3(8)	0(0)
Simultaneous Group	25(57)	22(61)	3(37)
Staged Group	19(43)	14(39)	5(62)
Days between procedures (Staged group)	72(IQR:57-87)	-	74(IQR:58-89)
Intraoperative details			
General Anesthesia TEVAR/EVAR	23(52)	15(42)	8(100)
Percutaneous femoral access TEVAR/EVAR	27(61)	24(67)	3(37)
Percutaneous femoral access TAVI	30(68)	26(72)	4(60)
Need for iliac adjunctive procedures	4(9)	4(11)	0(0)
Technical Success	44(100)	36(100)	8(100)

Post-operative results			
Cardiac adverse events	2(5)	1(3)	1(12)
Cerebrovascular adverse events	2(5)	1(3)	1 (12)
Respiratory adverse events	5(11)	2(6)	3(37)
Reinterventions	1(2)	1(3)	0(0)
Vascular access complication	2(5)	2(6)	0(0)
Death	1(2)	0(0)	1(12)

Table 6. Literature data about simultaneous TF-TAVI and EVAR.

Author	**Year**	**Cases**	**VAC**(n)	**30-day Mortality**(n)	**Hospitalization** (days)	**Follow-up** (moths)
Naoum	2023	6	2	0	8	19
Bramucci	2023	1	1	0	5	2
Yammine	2021	5	0	0	5	12
Koutsias	2020	2	0	0	9	18
Mauri	2019	2	1	0	10	9
Sato	2017	1	0	0	8	6
Kawashima	2016	1	0	-	9	-
Koudoumas	2015	1	0	0	3	3
Binder	2015	1	0	0	-	3
Aluko	2015	1	0	0	3	12
Marchi	2014	1	0	-	3	-
Chakraborty	2013	1	1	0	-	-
Smith	2012	1	0	0	5	-
Smith	2012	1	0	0	14	6
Overall		25	5	0	7	9
Present series	2023	25	1	0	7	25

VAC: vascular access complications; RF: renal function

REFERENCES

[1] Vahanian A, Beyersdorf F, Praz F, Milojevic M, Baldus S, Bauersachs J, et al. 2021 ESC/EACTS Guidelines for the management of valvular heart disease. European Heart Journal 2022;43:561–632. https://doi.org/10.1093/eurheartj/ehab395.

[2] Leon MB, Smith CR, Mack MJ, Makkar RR, Svensson LG, Kodali SK, et al. Transcatheter or Surgical Aortic-Valve Replacement in Intermediate-Risk Patients. N Engl J Med 2016;374:1609–20. https://doi.org/10.1056/NEJMoa1514616.

[3] Palmerini T, Saia F, Kim W-K, Renker M, Iadanza A, Fineschi M, et al. Vascular Access in Patients With Peripheral Arterial Disease Undergoing TAVR. JACC: Cardiovascular Interventions 2023;16:396–411. https://doi.org/10.1016/j.jcin.2022.12.009.

[4] Raju S, Eisenberg N, Montbriand J, Cusimano RJ, Feindel C, Ouzounian M, et al. Vascular Complications and Procedures Following Transcatheter Aortic Valve Implantation. European Journal of Vascular and Endovascular Surgery 2019;58:437–44. https://doi.org/10.1016/j.ejvs.2019.03.014.

[5] Toggweiler S, Leipsic J, Binder RK, Freeman M, Barbanti M, Heijmen RH, et al. Management of Vascular Access in Transcatheter Aortic Valve Replacement. JACC: Cardiovascular Interventions 2013;6:767–76. https://doi.org/10.1016/j.jcin.2013.05.004.

[6] Kurra V, Schoenhagen P, Roselli EE, Kapadia SR, Tuzcu EM, Greenberg R, et al. Prevalence of significant peripheral artery disease in patients evaluated for percutaneous aortic valve insertion: Preprocedural assessment with multidetector computed tomography. The Journal of Thoracic and Cardiovascular Surgery 2009;137:1258–64. https://doi.org/10.1016/j.jtcvs.2008.12.013.

[7] Czerny M, Grabenwöger M, Berger T, Aboyans V, Della Corte A, Chen EP, et al. EACTS/STS Guidelines for diagnosing and treating acute and chronic syndromes of the aortic organ. European Journal of Cardio-Thoracic Surgery 2024;65:ezad426. https://doi.org/10.1093/ejcts/ezad426.

[8] Wanhainen A, Van Herzeele I, Bastos Goncalves F, Bellmunt Montoya S, Berard X, Boyle JR, et al. European Society for Vascular Surgery (ESVS) 2024 Clinical Practice Guidelines on the Management of Abdominal Aorto-Iliac Artery Aneurysms. European Journal of Vascular and Endovascular Surgery 2024:S1078588423008894. https://doi.org/10.1016/j.ejvs.2023.11.002.

[9] Koutsias S, Karaolanis GI, Papafaklis MI, Peroulis M, Tzimas P, Lakkas L, et al. Simultaneous Transcatheter Aortic Valve Implantation and Infrarenal Aortic Aneurysm Repair for Severe Aortic Stenosis and Abdominal Aortic Aneurysm: Report of 2 Cases and Literature Review. Vasc Endovascular Surg 2020;54:544–8. https://doi.org/10.1177/1538574420927864.

[10] Cuschieri S. The STROBE guidelines. Saudi J Anaesth 2019;13:31. https://doi.org/10.4103/sja.SJA_543_18.

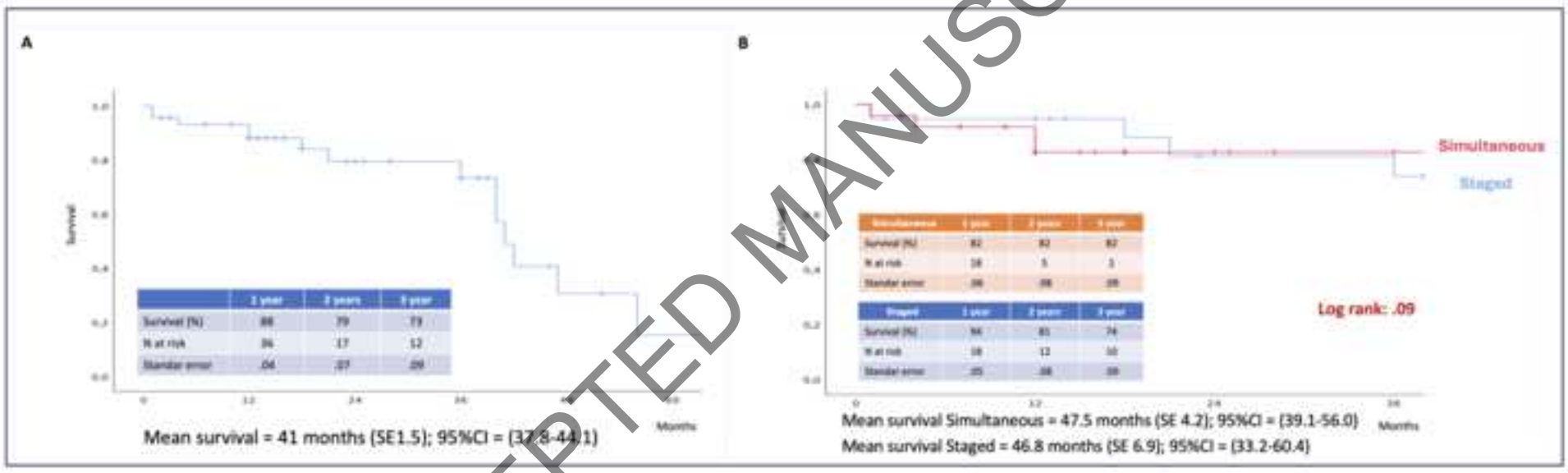
[11] Oderich GS, Forbes TL, Chaer R, Davies MG, Lindsay TF, Mastracci T, et al. Reporting standards for endovascular aortic repair of aneurysms involving the renal-mesenteric arteries. Journal of Vascular Surgery 2021;73:4S-52S. https://doi.org/10.1016/j.jvs.2020.06.011.

[12] VARC-3 WRITING COMMITTEE, Généreux P, Piazza N, Alu MC, Nazif T, Hahn RT, et al. Valve Academic Research Consortium 3: updated endpoint definitions for aortic valve clinical research. Eur Heart J 2021;42:1825–57. https://doi.org/10.1093/eurheartj/ehaa799.

[13] Bramucci A, Vignali L, Tadonio I, Losi L, Freyrie A, Perini P. Single-Stage Procedure of Transcatheter Aortic Valve Replacement and Endovascular Aneurysm Repair Under Local Anaesthesia and Percutaneous Access. Vasc Endovascular Surg 2023;57:949–53. https://doi.org/10.1177/15385744231183499.

[14] Grinberg T, Aviv Y, Vaturi M, Perl L, Wiessman M, Vaknin-Assa H, et al. Noninvasive Hemodynamic Evaluation Following TAVI for Severe Aortic Stenosis. JAHA 2023;12:e028479. https://doi.org/10.1161/JAHA.122.028479.
[15] Mauri S, Bozzani A, Ferlini M, Aiello M, Gazzoli F, Pirrelli S, et al. Combined Transcatheter Treatment of Severe Aortic Valve Stenosis and Infrarenal Abdominal Aortic Aneurysm in Increased Surgical Risk Patients. Annals of Vascular Surgery 2019;60:480.e1-480.e5. https://doi.org/10.1016/j.avsg.2019.03.028.
[16] Drury-Smith M, Garnham A, Khogali S. Critical aortic stenosis in a patient with a large saccular abdominal aortic aneurysm: Simultaneous Transcatheter Aortic Valve Implantation and Drive-by Endovascular Aortic Aneurysm Repair. Cathet Cardio Intervent 2012;80:1014–8. https://doi.org/10.1002/ccd.23452.
[17] Spath P, Campana F, Gallitto E, Pini R, Mascoli C, Sufali G, et al. Impact of iliac access in elective and non-elective endovascular repair of abdominal aortic aneurysm. J Cardiovasc Surg 2024. https://doi.org/10.23736/S0021-9509.24.12987-4.
[18] Jhaveri KD, Saratzis AN, Wanchoo R, Sarafidis PA. Endovascular aneurysm repair (EVAR)– and transcatheter aortic valve replacement (TAVR)–associated acute kidney injury. Kidney International 2017;91:1312–23. https://doi.org/10.1016/j.kint.2016.11.030.
[19] Spath P, Caputo S, Campana F, Gallitto E, Pini R, Mascoli C, et al. CO2 Angiography in the Standard and Complex Endovascular Repair of the Abdominal Aorta—A Narrative Review of the Literature. JCM 2024;13:4634. https://doi.org/10.3390/jcm13164634.
[20] Yammine H, Briggs CS, Rolle QV, Ballast JK, Frederick JR, Skipper E, et al. Simultaneous Transcatheter Aortic Valve Replacement and Endovascular Aortic Aneurysm Repair. Journal of the American College of Cardiology 2021;77:2156–7. https://doi.org/10.1016/j.jacc.2021.02.059.
[21] Naoum I, Eitan A, Galili O, Hayeq H, Shiran A, Zissman K, et al. Strategy for Totally Percutaneous Management of Vascular Injury in Combined Transfemoral Transcatheter Aortic Valve Replacement and Endovascular Aortic Aneurysm Repair Procedures. The American Journal of Cardiology 2023;207:130–6. https://doi.org/10.1016/j.amjcard.2023.08.148.

Figure 1



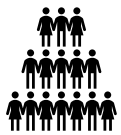
Central image

Simultaneous versus staged approach in transcatheter aortic valve implantation for severe stenosis and endovascular aortic repair for thoracic and abdominal aortic aneurysm.

Summary

Retrospective observational nationwide multicenter study, from 2016 to 2022, focused on patients presenting with TAA/AAA and concomitant severe aortic valve stenosis, submitted to T/EVAR associated to TAVI.

Patients divided in two groups if undergoing both procedures simultaneously or staged within 3-months. Primary outcomes were early mortality/morbidity; secondary outcomes were procedural data, LOS, follow-up survival.



44

25 = Simultaneous T/EVAR+TAVI

19 = Staged T/EVAR+TAVI

EARLY OUTCOMES

100% technical Success for all T/EVAR + TAVI

Mortality 1 case (2.2%)

Pulmonary complications (26% vs 0%;p=.01) and post-operative pace-maker (37% vs 8%;p=.02) more frequent in staged vs simultaneous patients.

SECONDARY OUTCOMES

No differences between staged vs simultaneous groups in intraoperative procedural outcomes.

LOS was shorter (7 days vs 19 days) in simultaneous patients (p=.001)

Comparable follow-up with 79% survival rate at 3-years.

CONCLUSIONS: T/EVAR + TAVI procedures are effective both in simultaneous or staged time-frame. Simultaneous repair seems to reduce length-of-stay and pulmonary complications, maintaining similar follow-up survival.

Legend: TAA=Thoracic Aortic Aneurysm; AAA=Abdominal Aortic Aneurysm; TEVAR=Thoracic Endovascular Aortic Repair; EVAR= Endovascular Aortic Repair; TAVI= Transcatheter Aortic Valve Implantation; LOS= Length of stay.