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Referring hospital involvement in early discharge post transcatheter aortic valve implantation: the TAVI (R-) EXPRES program

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Abstract

Aim: Over the past decade, transcatheter aortic valve implantation (TAVI) has matured into a valid treatment strategy for elderly patients with severe aortic stenosis. TAVI programs will grow with its adoption in low-risk patients. The aim of this study was to evaluate safety and feasibility of early discharge protocols, either home or back to a referring hospital.

Methods: Consecutive patients undergoing TAVI between July 2017 and July 2019 were stratified into three discharge pathways from TAVI center: (1) early home (EXPRES); (2) early transfer to referring hospital (R-EXPRES); and (3) routine discharge (standard). Baseline, procedural, and 30-day outcomes were prospectively collected and compared per discharge pathway.

Results: In total, 22 (5%) patients were enrolled in the EXPRES cohort [median age 78 (IQR: 73-81); mean Society of Thoracic Surgeons (STS) 2.4% \pm 1.5%], 121 (29%) in the R-EXPRES cohort [median age 81 (IQR: 77-84); mean STS 4.3% \pm 2.8%], and 269 (65%) in the routine discharge cohort [median age 80 (IQR: 75-85); mean STS 4.4% \pm 3.1%]. EXPRES patients trended to be younger (*P* = 0.13) and had lower STS (*P* = 0.02). Early clinical outcome was similar through the different pathways including re-hospitalization rate. Median length of stay was one day longer for R-EXPRES vs. routine discharge patients [5 (IQR: 4-7) vs. 4 (IQR: 3-6); *P* < 0.01]. Median length of stay (LOS) was two days (IQR: 1-3 days) for EXPRES patients.



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Conclusion: Early discharge pathways home and to referral hospitals are safe and help streamline TAVI programs. LOS in referring hospitals may be further reduced.

Keywords: Aortic valve stenosis, transcatheter aortic valve implantation, early discharge, length of stay

INTRODUCTION

Severe aortic stenosis is the most common valve disease requiring treatment in the Western world, and its prevalence is growing due to an ageing population^[1]. The only curative option for aortic stenosis is surgical or transcatheter valve implantation. Transcatheter aortic valve implantation (TAVI) is indicated for patients with a high or intermediate surgical risk^[2,3]. Recent trials have also shown TAVI feasibility in low surgical risk patients^[4,5]. Every patient requiring a bioprosthesis for aortic stenosis should now be informed about the transcatheter option.

As a result, the European and North American annual TAVI volume is expected to increase from 180,000 to 270,000 cases per year^[6]. Contemporary society guidelines recommend centralizing TAVI care in high-volume (> 85 procedures/year) sites because of an inverse volume-mortality correlation^[7]. To reconcile TAVI demand and supply and maintain high-quality healthcare at an affordable price, high-volume centers need to modify the TAVI cascade and streamline discharge policy. Early home discharge protocols aim to limit in-hospital stay to fewer than three days after TAVI with favorable early and mid-term outcomes and no penalty for readmissions or delayed need for definite pacemakers^[8].

For this purpose, we installed the TAVI EXpedited discharge Program Rotterdam EraSmus MC (TAVI EXPRES) and TAVI referral-EXPRES (TAVI R-EXPRES) programs in our institution. Various characteristics specific to the individual patient, the procedure, and the post-procedural recovery determine early discharge eligibility, either home or to a referring hospital. Early discharge protocols have been described, but thus far involvement of referring hospitals in the TAVI cascade has not been specifically studied^[9,10].

Early discharge to referring hospitals could optimize patient flow and bring post procedural quality care closer to (elderly) patients' home environment. The R-EXPRES program is a collaboration between the Erasmus MC and referring hospitals to organize patient work up before and care after TAVI in the referring hospital.

Herein, we report on the Rotterdam approach to promote early discharge home or to a referring hospital in the perspective of contemporary clinical practice and compare 30-day outcomes in different discharge pathways.

METHODS

Study population

All patients who underwent TAVI at the Erasmus MC between July 2017 and July 2019 and had complete 30-day follow-up were included. Patients were further identified in the TAVI EXpedited discharge Program Rotterdam Erasmus MC (EXPRES) and the referral EXPRES (R-EXPRES) program.

Patients who were deemed eligible for the EXPRES program were earmarked in the outpatient clinic by TAVI operators based on clinical criteria [Table 1]. These patients were then approached by a TAVI coordinating nurse who explained the "early discharge" concept, confirmed adequate social/familial

Table 1. Criteria for EXPRES eligibility

TAVI Strategy

Transfemoral approach Suitable for Edwards Sapien 3 or Acurate NEO Any TAVI device when permanent pacemaker is in place **Cardiac criteria should exclude** Poor systolic LV function defined by LVEF < 35% More than moderate tricuspid or mitral regurgitation Severe pulmonary hypertension (sPAP > 60 mmHg) Untreated high degree AV-block or RBBB **Pulmonary criteria should exclude** COPD Gold class > 2

Kidney criteria should exclude

eGFR < 35 mL/min

Frailty

Independent in Katz activities of daily living Presence of adequate social or family support

TAVI: Transcatheter aortic valve implantation; LVEF: left ventricular ejection fraction; sPAP: systolic pulmonary artery pressure; AV: atrioventricular; RBBB: right bundle branch block; COPD: chronic obstructive pulmonary disease; eGFR: estimated glomerular filtration rate.

support, and consented eligible candidates. For EXPRES patients without a pacemaker at baseline, preferably an Edwards Sapien S3 (Edwards Lifesciences Corp., Irvine, California) or Acurate NEO (Boston Scientific, Marlborough, Massachusetts) valve was implanted because these transcatheter heart valve (THV) platforms seem associated with the lowest risk for high-degree conduction disorders^[11,12].

Patients who were scheduled for early transfer to a referring hospital after the procedure were included in the R-EXPRES cohort. All patients were eligible for R-EXPRES except those who were enrolled in the EXPRES cohort. Patients were only transferred to the referring hospital if: (1) they were hemodynamically stable; (2) device success was confirmed; (3) there were no unresolved major procedure related complications; (4) there was no need for a temporary pacemaker; and (5) the referral hospital had logistics in place to accommodate patients post TAVI.

Study procedures

All patients were discussed in a multidisciplinary heart team including a cardiac surgeon, an interventional cardiologist, an imaging specialist, and a geriatrician. For R-EXPRES patients, all imaging, including transthoracic echocardiogram (TTE), multislice computed tomography, and coronary angiogram, was provided by the referring hospital. THV size and access strategy was determined by the valve center. All TAVI procedures took place at the heart valve center.

Discharge policy

The standard post-procedural clinical pathway consisted of daily electrocardiograms, laboratory assessment, and TTE pre discharge.

Patients earmarked for the EXPRES pathway were scheduled to be discharged home within 24 h unless longer observation was required (e.g., because of lingering conduction disorders or unresolved procedure related complications). They were followed up through phone calls one and seven days post discharge. Discharge policy was always left at the treating physician's discretion.

Patients in the R-EXPRES program were discharged to the referring hospital within 24 h in the absence of a temporary pace wire or unresolved major procedure-related complications.

Clinical outcomes and event screening

Baseline demographics, procedure characteristics, and in-hospital and 30-day clinical outcomes were collected in a dedicated prospective database. Discharge letters from referring hospitals were collected to determine length of stay (LOS) and screen for in-hospital events (for R-EXPRES patients). All patients were seen at the outpatient clinic 4-6 weeks after the procedure; clinical events that occurred between hospital discharge and 30-day follow-up were collected. All events were classified according to Valve Academic Research Consortium (VARC-2) definitions^[13].

Statistical analysis

Baseline characteristics are presented as numbers and percentages for categorical values. Continuous variables are presented as mean and standard deviation or median and interquartile range. Differences in baseline characteristics between cohorts were compared with analysis of variance for continuous variables and Pearson chi-square for categorical variables.

The percentage of new permanent pacemaker implantation was determined excluding patients with a pacemaker at baseline. Re-hospitalization rates for EXPRES and R-EXPRES cohorts were compared with the standard cohort using Fisher's exact test. Total LOS for R-EXPRES patients was compared with LOS for standard patients using Mann-Whitney *U* test.

RESULTS

From July 2017 to July 2019, 412 patients underwent successful implantation of at least one THV and had complete 30-day follow-up. A routine discharge pathway was followed in 269 patients (65%), while 121 patients were included in the R-EXPRES cohort (29%) and 22 in the EXPRES cohort (5%).

Baseline and procedural characteristics

Baseline characteristics stratified for discharge pathway are depicted in Table 2. In brief, EXPRES patients trended younger, were less symptomatic according to the New York Heart Association Classification (P < 0.01), and at lower estimated surgical risk according to Euroscore II (P < 0.01) and STS-score (P < 0.02) [Table 2].

Procedural characteristics are shown in Table 3. The vast majority of patients were treated through the femoral artery (93%, 95%, and 100% for the standard, R-EXPRES, and EXPRES cohorts, respectively). Almost all patients were treated under local anesthesia. There was an equal share of embolic protection use in all cohorts (44%, 45%, and 50% for the standard, R-EXPRES, and EXPRES cohorts, respectively, P = 0.86).

The share of balloon-expandable valves was higher in the EXPRES cohort as compared to the standard and R-EXPRES cohorts (73% *vs.* 41% and 36%; P < 0.01). Although EXPRES patients were treated with either an Edwards Sapien 3 or Acurate NEO valve per protocol, three patients underwent TAVI with the self-expanding Evolut Pro/R platform (Medtronic, Fridley, Minnesota): one because of inclusion in a registry on bicuspid valves and two due to small caliber femoral arteries [Table 3].

Clinical outcomes

Clinical outcomes are shown in Table 4. In total, seven (2%) patients died, one in the R-EXPRES cohort and six in the standard cohort. There were no deaths, stroke/transient ischemic attack, or access site

Table 2. Patient characteristics

Baseline characteristics	Standard	R-EXPRES	EXPRES	P-value	Total
	n = 269	n = 121	n = 22		n = 412
Age (years)	80 [75-85]	81 [77-84]	78 [73-81]	0.13	80 [75-85]
Male gender	146 (54)	61 (51)	14 (64)	0.49	221 (54)
Body mass index (kg/m ²)	27.3 ± 5.5	27.6 ± 5.4	26.2 ± 3.0	0.57	27.3 ± 5.4
Diabetes mellitus	86 (32)	38 (32)	5 (23)	0.67	132 (32)
Hypertension	190 (71)	83 (69)	14 (64)	0.76	287 (70)
Hypercholesterolemia	150 (56)	68 (57)	10 (46)	0.63	228 (55)
Creatinine (mmol/L)	113 ± 84	113 ± 69	86 ± 20	0.28	111 ± 78
Peripheral vascular disease	98 (36)	48 (40)	4 (18)	-	150 (36)
COPD	35 (13)	24 (20)	1(5)	-	60 (15)
Permanent pacemaker	35 (13)	10 (8)	0(0)	-	45 (11)
Prior coronary artery bypass graft	41 (15)	13 (11)	2 (9)	-	56 (14)
Prior percutaneous coronary intervention	75 (28)	34 (28)	3 (14)	0.34	112 (27)
Prior aortic valve surgery	8 (3)	3 (3)	0(0)	-	11 (3)
Prior cerebrovascular event	25 (9)	13 (11)	0(0)	-	38 (9)
New York Heart Association class ≥ III	146 (54)	74 (61)	2 (9)	< 0.01	222 (54)
Canadian Cardiovascular Society class ≥ II	52 (19)	24 (20)	6 (27)	-	82 (20)
European System for Cardiac Operative Risk Evaluation II (%)	5.3 ± 6.0	4.7 ± 4.1	2.0 ± 1.5	< 0.01	5.0 ± 5.4
Society of Thoracic Surgeons' score (%)	4.4 ± 3.1	4.3 ± 2.8	2.4 ± 1.5	0.02	4.2 ± 2.9

Categorical variables are presented as numbers (percentage). Continuous variables are presented as median (IQR) or mean ± SD. COPD: Chronic obstructive pulmonary disease.

Table 3. Procedural characteristics

Procedural characteristics	Standard	R-EXPRES	EXPRES	P-value	Total
	n = 269	n = 121	n = 22		n = 412
Transfemoral access	250 (93)	115 (95)	22 (100)	-	387 (94)
Transaxillary access	18 (7)	5 (4)	0(0)	-	23 (5.5)
Transapical access	1(0)	1 (1)	0 (0)	-	2 (0.5)
General anesthesia	12 (4)	1 (1)	0 (0)	-	13 (3)
Conscious sedation	4 (1)	0(0)	0(0)	-	4 (1)
Local anesthesia	253 (94)	120 (99)	22 (100)	-	395 (96)
Cerebral embolic protection	119 (44)	54 (45)	11 (50)	0.86	184 (45)
Single prosthetic valve implanted	263 (98)	118 (98)	22 (100)	-	403 (98)
- Balloon expandable	106 (41)	42 (36)	16 (73)	< 0.01	164 (41)
- Self- or mechanically expandable	156 (59)	76 (64)	6 (27)	< 0.01	238 (59)
Multiple valves implanted	6 (2)	3 (2)	0 (0)	-	9 (2)
Median procedural time (min)	67 [55-84]	60 [47-82]	69 [50-86]	0.15	66 [51-84]

Categorical variables are presented as numbers (percentage). Continuous variables are presented as median (IQR) or mean ± standard deviation (SD).

complications in the EXPRES cohort [Table 4].

Table 4.	Clinical	outcomes	at 30	days follow-up	
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Clinical outcomes	Standard	R-EXPRES	EXPRES	Total
	n = 269	n = 121	n = 22	n = 412
All-cause mortality	6 (2)	1 (1)	0(0)	7 (2)
Stroke	6 (2)	2 (2)	0(0)	8 (2)
Transient ischemic attack	4 (2)	1 (1)	0(0)	5 (1)
Access site complication	27 (10)	10 (8)	0(0)	37 (9)
Life-threatening bleeding	7 (3)	8 (7)	0(0)	15 (4)
Major bleeding	11 (4)	4 (3)	0(0)	15 (4)
Minor bleeding	16 (6)	3 (3)	1(5)	20 (5)
New permanent pacemaker ⁱ	42 (18)	20 (18)	1(5)	63 (17)
- Implanted at valve center		11 (55)		
- Implanted at referring hospital		9 (45)		
(I)CCU stay				
- No (I)CCU-stay	73 (27)	35 (29)	7 (32)	115 (28)
- < 24 h	163 (61)	72 (60)	14 (64)	249 (60)
- 24-48 h	23 (9)	9 (7)	1(4)	32 (8)
-≥48 h	9 (3)	4 (3)	0(0)	14 (3)
Median length of stay (total)	4 [3-6] ⁱⁱ	5 [4-7] ⁱⁱ	2 [1-3]	5 [3-6]
- Length of stay at valve center		1 [1-2]		
- Length of stay at referring hospital		4 [3-5]		
Re-hospitalization	19 (7) ^{iii,iv}	12 (10) ⁱⁱⁱ	3 (14) ^{iv}	34 (8)
- For heart failure	3 (1.1)	2 (1.7)	1(4.5)	6 (1.5)
- For conduction abnormalities	2 (0.7)	4 (3.3)	0(0)	6 (1.5)
- Infection	9 (3.3)	2 (1.7)	2 (9.1)	13 (3.2)
- Other reasons	5 (1.8)	4 (3.3)	0(0)	9 (2.2)

Categorical variables are presented as numbers (percentage). Continuous variables are presented as median (IQR). ⁱPacemakers at baseline were excluded; ⁱⁱP < 0.01; ⁱⁱⁱP = 0.45; ^{iv}P = 0.23.

The new permanent pacemaker implantation rate was 17% in the total cohort. In the R-EXPRES cohort, 20 patients (18%) required a new permanent pacemaker; 45% of the pacemakers were implanted in the referring hospital, while 55% of pacemakers were implanted at the heart valve center. One EXPRES patient needed a permanent pacemaker.

Although overall numbers were low, rates of re-hospitalization at 30 days for the R-EXPRES and EXPRES cohort were not different from the standard cohort (10% *vs.* 7%, P = 0.45, and 14% *vs.* 7%, P = 0.23, respectively). Twelve R-EXPRES patients (10%) were re-hospitalized, four because of conduction disorders, two because of heart failure, two because of infections, and four for various reasons (among them, two patients who collapsed without documented conduction disorders during telemetric observation). All four patients who were re-hospitalized because of conduction disorders required a permanent pacemaker. Three EXPRES patients were re-hospitalized: two patients required IV antibiotics (one because of pneumosepsis, the other because of a pacemaker lead infection) and one patient was readmitted due to heart failure. All three recovered [Figure 1].

R-EXPRES cohort

Of the 121 patients included in the R-EXPRES cohort, 14 patients (12%) did not go to the referring hospital. There was one intra-procedural death (hemodynamic collapse due to tamponade, unsuccessful resuscitation), three were discharged home because of quick recovery, nine faced unresolved complications,



Figure 1. Re-hospitalization rate stratified by cohort.

and one patient refused transfer. Of the unresolved complications, five had vascular or access-site related complications, two had unexplained neurological symptoms, and two had temporary pacemaker wires and went directly home after implantation of a permanent pacemaker in the valve center. One patient was discharged to the referring hospital but transferred back to the valve center after a complicated pacemaker implantation.

The remaining 105 patients (88%) went to the referring hospital. Median LOS for R-EXPRES patients was longer than that in the reference cohort [5 (IQR: 4-7) *vs.* 4 (IQR: 3-6); P < 0.01]. Median LOS in EXPRES was two days (IQR: 1-3 days).

DISCUSSION

TAVI thrives on meticulous patient selection, even more so when considering patients for early discharge. This single-center experience illustrates three discharge pathways including next day discharge from the TAVI site either home or to the referring hospital. The main findings of this single center experience with three different post-TAVI pathways can be summarized as follows: (1) a significant number of patients can be safely discharged home (EXPRES) or to the referral hospital (R-EXPRES) if proper logistics and/or social support are in place; (2) heart failure, conduction disorders, and infections were the main reasons for hospital re-admission; and (3) further data and experience exchange may streamline and reduce the LOS in the referral hospitals.

Early discharge

Changing patient phenotype to younger age with a more active and independent lifestyle demands an appropriate discharge policy. Over time, there has been a gradual reduction in LOS after TAVI, irrespective of surgical risk^[14]. The implementation of early discharge protocols as described in the Vancouver 3M and FAST-TAVI registries will further reduce LOS after TAVI.

Patients in the Vancouver 3M and FAST-TAVI registries on early discharge protocols were still elderly [84 (IQR: 78-87) and 81.4 (SD \pm 6.0), respectively]^[9,10]. Due to cultural differences and geographical differences

in addition to different reimbursement policies between countries, it is uncertain if such a progressive discharge policy in elderly will be accepted worldwide or is applicable for the majority of elderly, more dependent patients. Involving referring hospitals could alleviate TAVI expert centers by reducing prolonged in-hospital stay and bringing care closer to the patient's home environment. Barbanti *et al.*^[10] touched upon this option in FAST-TAVI. They showed feasibility of early discharge when adhering to a set of clinical discharge criteria; median LOS was two days (IQR: 1-4 days), and patients were either discharged home (79%) or to a referring hospital (16.2%). Our single-center cohort corroborates this concept of early transfer to a referring hospital as a specific discharge pathway.

Procedure simplification

Over the last couple of years, efforts to streamline the TAVI cascade have focused on various facets within the expert TAVI center including local anesthesia protocols, simplified TAVI execution, and reducing invasive instrumentation to a minimum. As such, in our cohort, 96% of the patients were treated under local anesthesia. Globally, there is a clear shift to perform transfemoral TAVI under local anesthesia/conscious sedation rather than general anesthesia^[15]. Local anesthesia is associated with shorter in-hospital and ICCU stays. Taking into account the heterogeneity of the patient population and selection bias, TAVI under local anesthesia shortens LOS by approximately 1.5 days when compared to general anesthesia^[16]. Moreover, procedural time and procedural turnover time can be substantially decreased. Shorter procedure time also precludes urinary catheter insertion, which minimizes the risk for urinary tract infections and bleeding^[17]. In our experience, median procedural time was approximately 1 h [66 min (51-84)], and there were no differences between the cohorts (P = 0.14).

Another important adjustment in our simplified TAVI protocol is to pace on the left ventricular guidewire with alligator clamps and no longer insert a temporary pacemaker through a deep venous access [Figure 2]. Only when a high-degree atrioventricular block occurs during the procedure, venous access for a temporary pacing wire in the right ventricular apex is obtained^[16].

Cerebral debris embolization is omnipresent in TAVI, and up to 90% of patients will develop brain injury, as demonstrated by post-TAVI brain magnetic resonance imaging. Use of filter-based cerebral embolic protection may cut new brain lesions after TAVI in half^[18]. We use embolic protection in all our patients when feasible. In this cohort, embolic protection was used in 45% of the cases. Reasons for not using an embolic protection device were: no calcium in the aortic annulus (e.g., in pure aortic regurgitation), transaxillary access, or unsuitable anatomy of the filter-landing zone.

In this contemporary cohort, access site related complications remained relevant (37 patients, 9%). The routine implementation of ultrasound guided femoral access may reduce access site complications; it precludes radiation and allows for real time visual monitoring of the vessel puncture. Notably, angiographic confirmation of successful closure device deployment after TAVI may further avoid covert retroperitoneal bleedings or flow limiting dissections and occlusions.

Re-hospitalization

In total, 34 patients (8%) were re-hospitalized. Heart failure (18%), conduction abnormalities (18%), and infections (38%) were the most common reasons. Our results are in line with previous reports on readmissions after TAVI, which have shown that, in more than half of the cases, the reason for readmission was non-cardiac^[19,20]. Infections remain an important issue after discharge, also in our study. Surgical cutdown of the femoral artery, overweight (BMI ≥ 25 kg/m²), bleeding complications, and ICCU stay have been identified as predictors for developing infections after TAVI^[21,22]. Modifiable factors such as avoiding surgical cutdown, in-dwelling (urinary) catheters, and shortening ICCU stay have been adjusted in our



Figure 2. Pacing over a left ventricular guidewire.

streamlined TAVI protocol. As such, the vast majority of patients did not go to the (I)CCU (n = 115, 28%) or were only observed for a period shorter than 24 h (n = 249, 50%). In addition, the number of patients who underwent TAVI through surgical cutdown of the femoral or subclavian artery was low (3% in total, results not shown). To further reduce respiratory and wound infections, patients should be actively mobilized and (I)CCU stay should become an exception instead of standard practice.

Of note, conduction disorders were the most frequent cause of readmission in the R-EXPRES cohort, which in our experience always required a permanent pacemaker. Ambulatory event monitoring after TAVI could further optimize discharge policy and detect conduction disorders before they cause harm. A recent pilot study showed an 8% incidence of delayed high-grade AV-block (≥ 2 days post-TAVI) with a median time to AV-block of six days (range 3-24 days)^[23].

Referring hospital involvement

Latest ESC guidelines on valvular heart disease recommend centralized TAVI care in heart valve expert centers^[2]. This recommendation specifically aims to centralize heart valve interventions including TAVI in order to maximize local experience and offer optimal procedure outcome. TAVI guidelines require heart valve centers to have specific institutional resources such as on-site cardiac surgeons and the capability of running cardiopulmonary bypass, which precludes the TAVI operator from performing the procedure at the referring hospital without these logistics in place. Therefore, we believe referring hospitals need to be involved in the work up before and care after TAVI to reinforce the concept and viability of expert heart valve centers and bring overall TAVI care closer to the patient's home environment.

Inter-hospital collaborations face specific challenges. In our study, LOS was one day longer for R-EXPRES patients compared to patients who were not transferred after TAVI [LOS: 5 (4-7) *vs.* 4 (3-6); P < 0.01]. This could suggest a knowledge and expertise gap between referring and TAVI expert centers and a lack of a harmonized protocol. Digital information transfer, shared electronic health records, and continued training and information exchange could further optimize this inter-hospital collaboration.

Limitations

Selection bias is an intrinsic limitation of every single-center retrospective analysis. The EXPRES cohort had a larger proportion of the Sapien and Acurate valve platforms: whether short LOS and equal re-hospitalization rate are attributed to patient selection rather than device selection is unsettled. In addition, this trial was performed before introduction of the cusp overlay technique, which could have influenced the

pacemaker rate with self-expandable valves^[24]. Discharge policy was defined by protocol but, in reality, per treating physician's discretion, and referring hospitals did not collect reasons for prolonged stay; variation in discharge policy among different physicians (e.g., due to difference in experience) might have influenced these results. However, to the best of our knowledge, this is the first study comparing three different discharge pathways. Our findings require confirmation in a prospective multicenter design.

Conclusions

Early discharge pathways home and to referral hospitals are safe and help streamline TAVI programs. LOS in referring hospitals may be further reduced.

DECLARATIONS

Authors' contributions

Study model design and study protocol writing: de Ronde-Tillmans MJ Experiment implementation: van Wiechen MP, de Ronde-Tillmans MJ Statistical analysis and first draft writing: van Wiechen MP Original idea conceiving and project supervision: Van Mieghem NM Critical feedback and research analysis: van Wiechen MP, de Ronde-Tillmans MJ, Van Mieghem NM

Availability of data and materials

The data that support the findings of this study are available from the corresponding author upon reasonable request.

Financial support and sponsorship

None.

Conflict of interest

Nicolas M. Van Mieghem received research grants from Abbott, Boston Scientific, Edwards, Essential Medical/Teleflex, Medtronic, PulseCath BV. All other authors declared there are no conflict of interest.

Ethical approval and consent to participate

The study was conducted in accordance with the declaration of Helsinki and did not fall under the scope of the Medical Research Involving Human Subjects Act. All patients consented to the procedure and subsequent data analysis for research purposes.

Consent for publication

All participants provided informed consent for the publication.

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