Canadian Journal of Cardiology 35 (2019) 199–207

Clinical Research

Impact of Discharge Location After Transcatheter Aortic Valve Replacement on 1-Year Outcomes in Women: Results From the WIN-TAVI Registry

Julinda Mehilli, MD,[a,*] Jaya Chandrasekhar, MBBS, MS,[b,*] Samantha Sartori, PhD,[b] Alaide Chieffo, MD,[c] Anna S. Petronio, MD,[d] Thierry Lefèvre, MD,[e] Patrizia Presbitero, MD,[f] Piera Capranzano, MD,[g] Didier Tchetche, MD,[h] Alessandro Iadanza, MD,[i] Gennaro Sardella, MD,[j] Nicolas M. Van Mieghem, MD, PhD,[k] Emanuela Meliga, MD,[l] Nicolas Dumonteil, MD,[m] Chiara Fraccaro, MD, PhD,[n] Daniela Trabattoni, MD,[o] David Jochheim, MD,[a] Magda Zadrozny, MD,[a] Ghada W. Mikhail, MD,[p] Samin Sharma, MD,[q] Maria C. Ferrer, MD,[r] Christoph Naber, MD,[s] Peter Kievit, MD,[t] Kamilia Moalem, BS,[b] Usman Baber, MD, MS,[b] Clayton Snyder, BS,[b] Madhav Sharma, MBBS,[b] Marie C. Morice, MD,[e] and Roxana Mehran, MD;[b] on behalf of the Women's INternational Transcatheter Aortic Valve Implantation (WIN-TAVI) Investigators

[a] Munich University Clinic, Ludwig-Maximilians-University and German Centre for Cardiovascular Research (DZHK), partner site Munich Heart Alliance, Munich, Germany; [b] Icahn School of Medicine at Mount Sinai, New York, New York, USA; [c] San Raffaele Scientific Institute, Milan, Italy; [d] AOUP Cisanello, University Hospital, Pisa, Italy; [e] Institut Hospitalier Jacques Cartier, Ramsay Générale de Santé, Massy, France; [f] Istituto Clinico Humanitas, Milan, Italy; [g] University of Catania, Catania, Italy; [h] Clinique Pasteur, Toulouse, France; [i] Azienda Ospedaliera Universitaria Senese, Policlinico Le Scotte, Siena, Italy; [j] Policlinico "Umberto I", "Sapienza" University of Rome, Rome, Italy; [k] Erasmus Medical Center, Thorax center, Rotterdam, The Netherlands; [l] Mauriziano Hospital, Turin, Italy; [m] Rangueil University Hospital, Toulouse, France; [n] University of Padova, Padova, Italy; [o] Centro Cardiologico Monzino, Milan, Italy; [p] Imperial College Healthcare NHS Trust, Hammersmith Hospital, London, United Kingdom; [q] Mount Sinai Hospital, New York, New York, USA; [r] Hospital Universitario Miguel Servet, Zaragoza, Spain; [s] Contilia Heart and Vascular Centre, Elisabeth Krankenhaus, Essen, Germany; [t] Radboud University Nijmegen Medical Center, The Netherlands

ABSTRACT

Background: Several clinical and procedural factors determine outcomes after transcatheter aortic valve replacement (TAVR), but data are scarce on the impact of post-TAVR discharge disposition on long-term outcomes. We sought to analyse whether discharge location after TAVR is associated with 1-year outcomes in women undergoing contemporary TAVR.

Methods: The Women's INternational Transcatheter Aortic Valve Implantation (WIN-TAVI) registry is the first all-female TAVR registry to study the safety and performance of contemporary TAVR in women

RÉSUMÉ

Contexte : Plusieurs facteurs d'ordre clinique et procédural déterminent les résultats d'un remplacement valvulaire aortique par cathéter (RVAC), mais rares sont les données sur les conséquences des dispositions prises lors du congé post-RVAC sur les résultats à long terme. Nous avons voulu déterminer si le lieu du congé consécutif à un RVAC est associé à certains résultats après 1 an chez des femmes ayant subi un RVAC selon des techniques de dernière génération.

Méthodologie : Le registre *Women's INternational Transcatheter Aortic Valve Implantation* (WIN-TAVI), le premier registre de patients

Transcatheter aortic valve replacement (TAVR) is a standard of care procedure for the treatment of significant symptomatic aortic stenosis (AS).[1-3] During the last decade, TAVR indication has been broadened toward intermediate-risk patients,[4,5] while keeping the mean age of TAVR-suitable patients above 80 years. Device improvements and simplification of procedures have substantially reduced the risk of complications after TAVR; however, 1-year mortality risk

Received for publication August 5, 2018. Accepted November 22, 2018.

*These authors contributed equally to this work.

Corresponding author: Dr Roxana Mehran, The Zena and Michael A. Wiener Cardiovascular Institute, The Icahn School of Medicine at Mount Sinai, One Gustave L. Levy Place, Box 1030, New York, New York 10029-6574, USA. Tel: +1-212-659-9691; fax: +1-646-537-8547.

E-mail: Roxana.mehran@mountsinai.org

See page 206 for disclosure information.

https://doi.org/10.1016/j.cjca.2018.11.035

(n = 1019). Information on discharge location was available in 817 patients (80.2%). We compared women discharged home vs those discharged to another location (nursing home, rehabilitation, or other hospital). One-year outcomes were adjusted using multivariable Cox regression methods with discharge home as the reference group.

Results: Of the study subjects, 75.2% (n = 614) were discharged home and 24.8% (n = 203) to another location. Women discharged to other locations were older with a greater prevalence of severe lung disease requiring home oxygen and renal failure on dialysis but were less frequently considered frail or at high surgical risk compared with women discharged home. After multivariable adjustment, non-home discharge was associated with greater hazard for 1-year Valve Academic Research Consortium 2 efficacy (21.3% vs 10.8%, hazards ratio [HR] 1.9, 95% confidence interval [CI] 1.2-2.9) and safety endpoints (31.5% vs 15.2%, HR 2.1, 95% CI 1.5-3.0), cardiovascular death (12.7% vs 5.5%, HR 2.0, 95% CI 1.1-3.6), and stroke (6.5% vs 0.8%, HR 8.5, 95% CI 2.9-25.6).

Conclusions: In women undergoing contemporary TAVR, discharge disposition significantly affects 1-year risk of outcomes even after adjustment for recorded baseline differences. This might suggest the necessity of considering additional factors beyond comorbidities in the TAVR decision-making process.

ayant subi un RVAC ne portant que sur des femmes, a été constitué pour étudier l'innocuité et l'efficacité du RVAC selon les techniques de dernière génération chez les femmes (N = 1019). L'information sur la destination des patientes après leur congé était connue pour 817 patientes (80,2 %). Nous avons comparé les femmes qui regagnaient leur domicile après leur congé et celles qui étaient dirigées vers un autre établissement (foyer de soins infirmiers, centre de réadaptation ou autre hôpital). Les résultats après un an ont été ajustés par des méthodes de régression multivariée de Cox où le groupe de référence était celui du retour au domicile après le congé de l'hôpital.

Résultats : Parmi les participantes, 75,2 % (n = 614) ont regagné leur domicile après leur congé et 24,8 % (n = 203) ont été dirigées vers un autre établissement. Les femmes de ce dernier groupe étaient plus âgées, affichaient une prévalence plus élevée de maladie pulmonaire grave nécessitant une oxygénothérapie à domicile et d'insuffisance rénale sous dialyse, mais étaient moins souvent considérées comme étant fragiles ou présentant un risque élevé en cas de chirurgie que celles qui avaient regagné leur domicile. Après ajustement multivarié, l'aiguillage vers un autre établissement après le congé était associé à un risque plus élevé quant aux critères d'évaluation à 1 an de l'efficacité (21,3 % vs 10,8 %, rapport des risques instantanés [RRI] 1,9, intervalle de confiance [IC] à 95 %, de 1,2 à 2,9) et de l'innocuité (31,5 % vs 15,2 %, RRI 2,1, IC à 95 %, de 1,5 à 3,0), du Valve Academic Research Consortium-2, au décès d'origine cardiovasculaire (12,7 % vs 5,5 %, RRI 2,0, IC à 95 %, de 1,1 à 3,6) et à l'accident vasculaire cérébral (6,5 % vs 0,8 %, RRI 8,5, IC à 95 %, de 2,9 à 25,6).

Conclusions : Chez les femmes ayant subi un RVAC selon des techniques de dernière génération, la destination après le congé de l'hôpital a une incidence significative sur le risque à 1 an des résultats, même après ajustement en fonction des différences enregistrées au début de l'étude. Ces observations laissent croire qu'il pourrait être utile de prendre en compte des facteurs additionnels autres que les comorbidités dans le processus de prise de décision au sujet du RVAC.

remains high among this elderly population.[6] Therefore, patient selection remains the central focal point for heart teams and TAVR centres. Based on the results from the **P**lacement of **A**ortic **T**ra**n**scathet**er** Valves (PARTNER) I trial, TAVR is now not recommended in prohibitive-risk patients who are unlikely to gain sufficient quality of life.[7] Deriving from studies that included patients younger than the typical TAVR population who underwent cardiac surgery, risk scores used to determine TAVR suitability are mostly based on aggregation of comorbidities.[8,9] Therefore, other factors such as patient frailty have become important for determining TAVR risk. On the other hand, TAVR outcomes are not only limited to the procedure but also influenced by post-TAVR management and care. An important component of post-TAVR care in this elderly patient population is care out of hospital to improve physical level of activity and thereby optimize functionality. Nearly 50% of patients undergoing TAVR are women, who are more often observed to be frail and at higher risk.[10] Given these concepts, we wanted to examine the patient characteristics and outcomes after TAVR in women discharged home vs those discharged to an alternative location including discharge to a rehabilitation or other hospital type, or discharge to a nursing home. We studied the all-female **W**omen's **In**ternational **T**ranscatheter **A**ortic **V**alve **I**mplantation (WIN-TAVI) registry[6,10] for these aims and present our outcomes in the current report.

Methods

The WIN-TAVI registry is an international, multicentre, prospective, observational study of women undergoing TAVR at 18 European and 1 North American centre treated with commercially available and approved TAVR devices for the treatment of severe symptomatic AS (ClinicalTrials.gov Identifier: NCT01819181).[6,10] Participating centres were chosen based on the review of site-selection survey responses to determine the total number of TAVR performed at each centre (at least 50) and the planned number of TAVR to be performed in the following year. All sites had local ethics committee approval, and the study was conducted according to the principles of the Declaration of Helsinki, Good Clinical Practice and International Organization for Standardization Guidelines.

All patients who met the eligibility criteria were enrolled after written informed consent. The study was conducted without external funding and was successfully completed based on the academic interest of the investigators. The protocol and study endpoints were agreed on by the executive committee and principal investigators of the study.

Eligibility criteria

The eligibility criteria are published in detail elsewhere.[10] In brief, women with (1) severe AS determined by

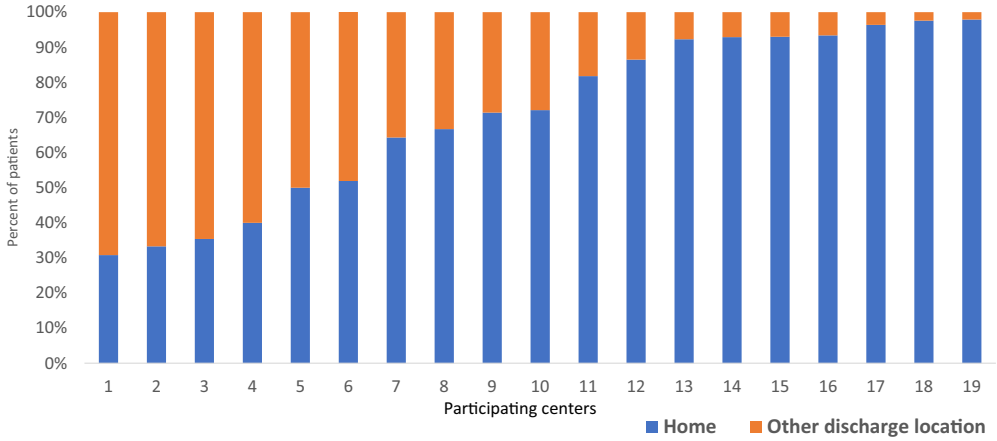

Figure 1. Frequency of home or other discharge locations across the 19 participating centres. The *y*-axis represents percentage of patients discharged home or to other discharge locations; the *x*-axis represents participating centres in the study.

echocardiography defined as mean gradient $>$ 40 mm Hg or peak jet velocity $>$ 4.0 m/s and an aortic valve area $\leq$ 0.8 cm^2 or aortic valve area index $\leq$ 0.5 cm^2/m^2 and (2) symptoms of angina, congestive heart failure New York Heart Association functional class $\geq$ II, or syncope were considered for enrollment if no exclusions applied.

Additional inclusion criteria were based on high EuroSCORE or the presence of other comorbidities (such as chronic lung disease, treatment with home oxygen, porcelain aorta, prior thoracic radiotherapy, Child Pugh class B and C liver disease), resulting in heart team decision for TAVR. The main exclusions were untreated clinically significant ($>$ 70% obstruction) proximal vessel coronary artery disease amenable to revascularization, haemodynamic instability (eg, requiring inotropic support), active endocarditis or sepsis within 6 months before the study procedure or use of an investigational device without Conformité Européene mark.

TAVR procedure and follow-up

Pre-TAVR screening included evaluation of medical history and imaging undertaken per standard of care (transthoracic/transesophageal echocardiogram and/or multidetector computed tomography). We also collected data on female-specific factors: menstrual history, use of hormone replacement therapy, history of pregnancy, osteoporosis, gynecological, or breast cancer.

Procedural decisions regarding access, device type, pre- and postdilation, and associated therapies during TAVR were at the discretion of the operating physicians. Post-TAVR follow-up was conducted by trained research staff via telephone or clinic visit at 1 month, 6 months, and 12 months to record clinical status and endpoint adverse events. Total planned follow-up is to 24 months. Per standard of care patients underwent neurologic evaluation and imaging after TAVR at the participating sites only if clinically indicated.

The Clinical and Data coordinating centre for the study was at the Icahn School of Medicine at Mount Sinai, New York, USA, which was responsible for the monitoring of data entry into the electronic data capture system, accuracy of data, database and data management, and statistical analyses. All events were adjudicated by an independent Clinical Events Committee using source documents provided by the sites. The study was endorsed by the Society for Cardiovascular Angiography and Interventions-Women in Innovation (SCAI-WIN) initiative.

Study endpoints and definitions

Primary endpoint. The primary efficacy endpoint was the Valve Academic Research Consortium (VARC) 2 composite of all-cause mortality, all stroke, myocardial infarction, hospitalizations for valve-related symptoms, or worsening congestive heart failure.[11] The primary safety endpoint was the VARC 2 composite of all-cause mortality, all stroke, life-threatening bleeding, stage 2 or 3 acute kidney injury, coronary artery obstruction requiring intervention, major vascular complications, or repeat procedure for valve-related dysfunction.

Study definitions. Endpoints were adjudicated using the standardized VARC-2 criteria.[11] Frailty was subjective as judged by the heart team, but the use of objective frailty scales was recommended. Old-generation devices comprised Edwards SAPIEN XT and Medtronic CoreValve. All other prosthesis types are considered new-generation devices. History of pregnancy was defined as any history of pregnancy and not specifically pregnancy resulting in a live birth.

Statistical approach

Groups were compared based on discharge location home vs other. Categorical data are presented as frequencies and percentages and were compared using the χ^2 or Fisher's exact test. Continuous variables are presented as means and standard deviation, or medians and interquartile ranges and were compared using the Student *t* test or Wilcoxon signed-rank test. Time-to-event curves were represented using Kaplan-Meier methods and time-to-event outcomes compared using the log rank test. Using Cox regression methods, we generated a multivariable model for risk of 1-year outcomes with discharge to other locations (reference = discharge home). We included covariates with univariate associations with $P < 0.20$ in a

Table 1. Baseline characteristics

	Discharge home (N = 614)	Other discharge location (N = 203)	*P* value
Age (y)	82.1 ± 6.5	83.4 ± 5.9	0.01
Caucasian	588 (95.8)	197 (97.0)	0.42
BMI (kg/m^2)	26.1 ± 5.2	25.6 ± 5.8	0.27
Hypertension	518 (85.3%)	149 (74.5%)	< 0.001
Diabetes mellitus	164 (26.8%)	53 (26.1%)	0.84
Current smoker	19 (3.1%)	5 (2.5%)	0.64
Previous PCI	135 (22.1%)	56 (27.6%)	0.11
Previous CABG	42 (6.9%)	9 (4.4%)	0.21
Prior other cardiac surgery	77 (12.6%)	16 (7.9%)	0.07
Atrial fibrillation on baseline ECG	129 (21.4%)	39 (20.0%)	0.62
Prior stroke	41 (6.7%)	15 (7.4%)	0.74
CKD	181 (30.1%)	66 (32.8%)	0.47
Prior PAD	60 (10.0%)	17 (8.5%)	0.54
EuroSCORE I (%)	17.5 ± 12.0	18.1 ± 10.7	0.58
STS score (%)	8.1 ± 7.5	9.0 ± 7.3	0.16
Permanent pacemaker	55 (9.0%)	15 (7.4%)	0.49
Labs			
Haemoglobin (g/dL)	11.8 ± 1.7	11.9 ± 1.7	0.35
Creatinine (mg/dL)	1.1 ± 0.7	2.0 ± 7.6	0.01
LV ejection fraction (%)	55.8 ± 10.8	56.0 ± 10.5	0.82
Discharge medications			
Aspirin	449 (76.2%)	157 (83.1%)	0.049
P2Y12 inhibitor	389 (65.7%)	108 (57.1%)	0.033
Oral anticoagulant	168 (28.4%)	47 (24.9%)	0.34
DAPT	315 (53.5%)	93 (49.2%)	0.31
Triple therapy	24 (4.1%)	5 (2.7%)	0.37
Discharge information			
Length of stay (d)	11.6 ± 7.8	13.5 ± 8.3	0.0057
ICU stay duration (d)	2.1 ± 2.4	3.7 ± 3.9	< 0.0001

Data are shown as mean ± SD or number (%).

BMI, body mass index; CABG, coronary artery bypass grafting; CKD, chronic kidney disease; DAPT, dual antiplatelet therapy; ECG, electrocardiography; ICU, intensive care unit; LV, left ventricle; PAD, peripheral arterial disease; PCI, percutaneous coronary intervention; SD, standard deviation; STS, Society of Thoracic Surgeons.

multivariable model using stepwise selection ($P_{entry} < 0.10$, $P_{exit} < 0.20$), and country as a random effect. All analyses were performed using Stata version 14.0 (College Station, TX), and *P* values < 0.05 were considered significant.

Results

Study population

From January 2013 to December 2015, 1019 women were enrolled across 18 centres in Europe and 1 centre in North America. One-year follow-up was achieved in 98.8% of eligible patients. Of these, discharge location was available in 817 patients, 75.2% (n = 614) were discharged home, and 24.8% (n = 203) were discharged to another location. Figure 1 shows the frequency of patients discharged home or other discharge locations in the 19 participating centres.

The baseline and procedural characteristics are shown in Tables 1 and 2.

Patients discharged to other locations were somewhat older with a numerically greater prevalence of prior percutaneous coronary intervention, significantly greater severe lung disease, and dialysis or renal failure but similar left ventricular ejection fraction, similar rate of baseline atrial fibrillation, and mean

Table 2. Procedural characteristics and complications

	Discharge home (N = 614)	Other discharge location (N = 203)	*P* value
Number of diseased coronary arteries on angiography			0.94
0	265 (62.7%)	98 (61.3%)	
1	77 (18.2%)	28 (17.5%)	
2	38 (9.0%)	17 (10.6%)	
3	43 (10.2%)	17 (10.6%)	
Left main disease ≥50%	21 (5.8%)	8 (5.6%)	0.96
Valve predilation	409 (67.4%)	163 (81.5%)	< 0.0001
Device postdilation	86 (14.3%)	31 (15.3%)	0.73
Pacing during valve deployment	375 (64.0%)	142 (72.8%)	0.024
Contrast volume (mL)	160.2 ± 83.3	146.5 ± 90.0	0.074
Inotropes	19 (3.3%)	8 (4.1%)	0.59
Blood products	28 (4.8%)	24 (12.2%)	< 0.0001
Intra-aortic balloon pump	1 (0.2%)	0 (0.0%)	0.56
Access site			< 0.001
Transfemoral	577 (94.0%)	162 (79.8%)	
Nontransfemoral	37 (6.0%)	41 (20.2%)	
Access technique			< 0.001
Percutaneous	551 (89.7%)	156 (76.9%)	
Surgical cutdown	63 (10.3%)	47 (23.2%)	
Sheath size			0.05
≤ 18 F	382 (64.8%)	141 (72.3%)	
> 18 F	208 (35.3%)	54 (27.7%)	
Device size			0.06
≤ 26 mm	500 (82.6%)	155 (76.7%)	
> 26 mm	105 (17.4%)	47 (23.3%)	
Closure device used			0.38
Prostar	268 (46.6%)	72 (40.7%)	
Proglide	233 (40.5%)	79 (44.6%)	
Other	74 (12.9%)	26 (14.7%)	
Device generation			0.002
New	266 (45.6%)	65 (32.8%)	
Old	317 (54.4%)	133 (67.2%)	
Device type			0.004
Edwards SAPIEN 3	140 (24.0%)	45 (22.7%)	
Edwards SAPIEN XT	94 (16.1%)	52 (26.3%)	
Medtronic Evolut R	49 (8.4%)	4 (2.0%)	
Medtronic CoreValve	223 (38.3%)	81 (40.9%)	
Direct Flow	23 (4.0%)	5 (2.5%)	
Portico	6 (1.0%)	2 (1.0%)	
Lotus	44 (7.6%)	8 (4.0%)	
Symetis ACURATE Neo	4 (0.7%)	1 (0.5%)	
Procedural complications			
Valve embolization	8 (1.3%)	3 (1.5%)	0.87
Annulus or aortic rupture	6 (1.0%)	1 (0.5%)	0.50
Pericardiocentesis	7 (1.2%)	1 (0.5%)	0.41
Ventricular perforation	4 (0.7%)	3 (1.5%)	0.28
Complete AV block	46 (7.7%)	19 (9.4%)	0.43
Post-TAVR AR grade 2 or 3	38 (7.0%)	11 (5.9%)	0.86

Data are shown as mean ± SD or number (%).

AR, aortic regurgitation; AV, atrioventricular; SD, standard deviation; TAVR, transcatheter aortic valve replacement.

EuroSCORE I. However, they were less often considered to be frail or at high surgical risk. Figure 2 shows the differences in key reasons for TAVR by discharge location.

Procedurally significant differences were noted. Other discharge location patients more often underwent non-transfemoral access with surgical cutdown, a lower rate of use of new generation devices with mostly balloon-expandable devices and more frequent use of device size > 26 mm. Despite this, there were no differences in postprocedural aortic regurgitation. The incidence of procedural complications was also similar between the 2 groups; however, the rate of blood

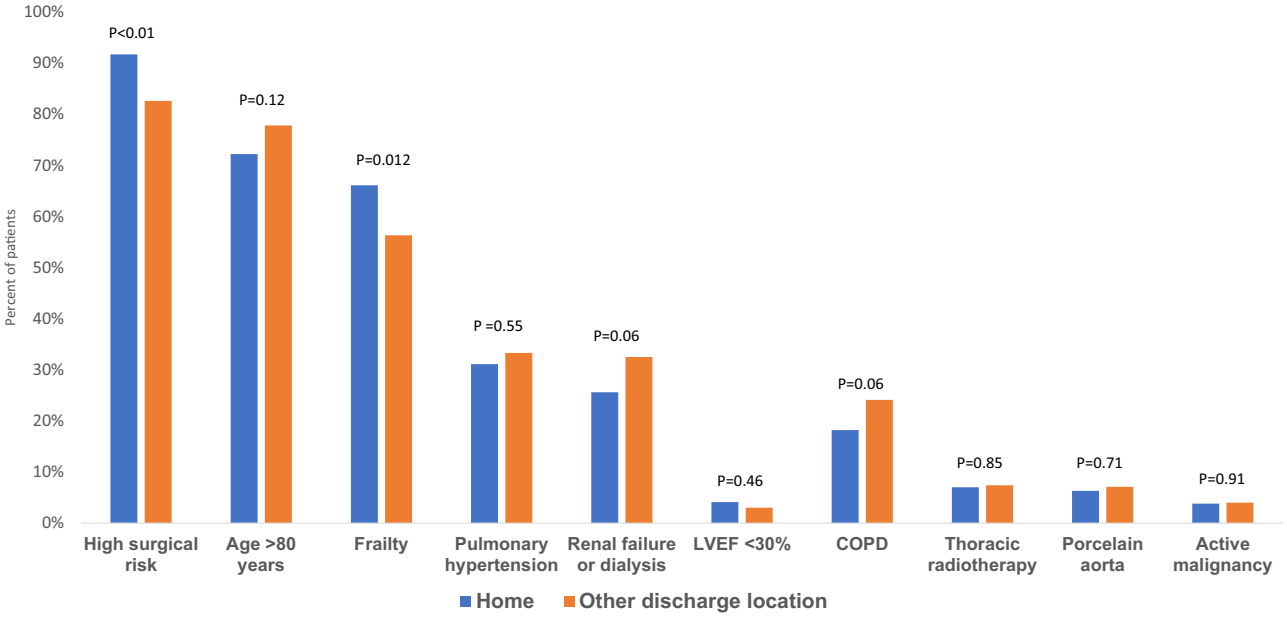

Figure 2. Key reasons for undergoing TAVR in patients discharged home vs other discharge locations. COPD, chronic obstructive lung disease; LVEF, left ventricular ejection fraction; TAVR, transcatheter aortic valve replacement.

product transfusion was greater in other discharge location patients (Table 2). These patients also had longer in-hospital and intensive care unit stay (Table 1). Supplemental Figure S1 presents the distribution of other location discharge and non-transfemoral access TAVR patients by site.

The 30-day and 1-year clinical outcomes are shown in Table 3. Cumulative incidences of Kaplan-Meier event rates are shown in Figure 3. At 30 days, patients discharged to other locations demonstrated a greater incidence of the primary efficacy composite endpoint (8.4% vs 1.3%, $P < 0.001$), primary safety endpoint (22.2% vs 8.1%, $P < 0.001$), and other individual clinical outcomes. Similarly, at 1 year, patients discharged to other locations had a significantly greater incidence of the VARC-2 efficacy (21.3% vs 10.8%, $P < 0.001$) and safety (31.5% vs 15.2%, $P < 0.001$) endpoints, as well as death, cardiovascular death, new onset atrial fibrillation, stroke, and composite outcomes. After adjustment for known confounders including access site, these risks remained significantly higher than patients discharged home (Fig. 4). In a sensitivity analysis among patients undergoing transfemoral access only, results remained unchanged (Supplemental Table S1).

Discussion

This analysis of the WIN-TAVI registry is among the first few studies dedicated to the impact of discharge location on outcomes among women after TAVR. We found that compared with women discharged home, women with non-home discharge locations after TAVR: (1) are older, present more frequently with severe lung disease requiring home oxygen and renal failure on dialysis but are less frequently considered frail or at high surgical risk; (2) more frequently undergo transapical TAVR and have higher rates of bleeding and vascular complications after TAVR requiring blood transfusion; (3) experience a significantly greater incidence of the primary efficacy and safety endpoints, death, new onset atrial fibrillation, stroke, and death or stroke at 1 year. Thus, even after adjustment for known confounders, discharge to other locations is associated with greater risk of adverse outcomes at 1 year after TAVR.

Although TAVR is now widely performed and is recommended as an alternative approach to surgical aortic valve replacement in patients with intermediate- or high-risk AS,[2-5] it remains an expensive undertaking. Certainly, TAVR management encompasses the rigors of careful preselection, the procedure itself, and postprocedural care. Given the important risks and costs, TAVR is not recommended in prohibitive-risk patients who are unlikely to regain adequate quality of life, thus multidisciplinary heart teams consider several selection criteria to determine patient frailty.[1,12] Frailty assessment entails the use of cumbersome scales that, although objective, are not yet easy to apply in this elderly patient population during a busy practice.[12-14] Recently however, in the FRAILTY-AVR study, Afilalo et al.[15] showed that the Essential Frailty Toolset score, a relatively easy-to-use measure comprising the presence of cognitive impairment, ability to perform chair rises, haemoglobin, and albumin laboratory values, was a strong predictor of 1-year disability after TAVR. Although social factors and need for post-TAVR rehabilitation are considered in pre-TAVR discussions, systematic data collection and analysis of these factors towards planning of potential discharge location is lacking. As we show from the current study, thoughtful evaluation of issues related to postprocedural discharge location should be a mandatory component of heart team discussions.

In our analysis, women who were not discharged home were found to have greater baseline risk factors including chronic obstructive lung disease, chronic kidney disease, and older age that have been shown to be independently associated with high morbidity and mortality. Yet, interestingly we observed that these patients were less likely to be considered

Table 3. Thirty-day and one-year clinical outcomes

	Discharge home (N = 614)	Other discharge location (N = 203)	*P* value
30-d outcomes			
VARC 2 efficacy endpoint	8 (1.3%)	17 (8.4%)	< 0.001
VARC 2 safety endpoint	50 (8.1%)	45 (22.2%)	< 0.001
Bleeding			
Life threatening	14 (2.3%)	14 (6.9%)	0.0017
Major	57 (9.3%)	39 (19.2%)	0.0001
Major vascular complications	39 (6.4%)	24 (11.8%)	0.0113
Death	4 (0.7%)	7 (1.3%)	0.0026
Cardiovascular death	3 (0.5%)	6 (3.0%)	0.0034
MI	1 (0.2%)	1 (0.5%)	0.2101
Stroke	1 (0.2%)	7 (3.5%)	< 0.001
Death or stroke	5 (0.8%)	14 (6.9%)	< 0.001
Death, MI, or stroke	5 (0.8%)	15 (7.4%)	< 0.001
Death, MI, stroke, or life-threatening bleeding	18 (2.9%)	25 (12.3%)	< 0.001
AKI stage 2 or 3	5 (0.8%)	4 (2.0%)	0.17
Any arrhythmia or conduction disturbance	132 (21.5%)	48 (23.7%)	0.53
New atrial fibrillation or flutter	12 (2.0%)	9 (4.4%)	0.052
New pacemaker	65 (10.6%)	33 (16.3%)	0.0346
1-y outcomes			
VARC 2 efficacy endpoint	66 (10.8%)	43 (21.3%)	<0.001
VARC 2 safety endpoint	93 (15.2%)	64 (31.5%)	<0.001
Death or stroke	49 (8.0%)	39 (19.4%)	<0.001
Death, MI, stroke	54 (8.9%)	40 (19.9%)	<0.001
Death, MI, stroke, life-threatening bleeding	65 (10.7%)	50 (24.9%)	<0.001
Stroke	5 (0.8%)	13 (6.5%)	<0.001
MI	8 (1.3%)	1 (0.5%)	0.34
Death	45 (7.4%)	30 (15.0%)	0.0012
Cardiovascular death	33 (5.5%)	25 (12.7%)	0.0006
New atrial fibrillation or flutter	14 (2.3%)	11 (5.4%)	0.024
New PPM	72 (11.7%)	34 (16.8%)	0.07
Any arrhythmia or conduction disturbance	138 (22.5%)	48 (23.7%)	0.72

Data are shown as n (Kaplan-Meier %).

AKI, acute kidney injury; MI, myocardial infarction; PPM, permanent pacemaker; VARC, Valve Academic Research Consortium.

frail or at high surgical risk by heart teams before TAVR. Indeed, more of these women underwent TAVR via nontransfemoral access (20% vs 6%) with greater use of older generation devices (67.2% vs 54.4%), which may be related to the fact that new generation devices were not equally available for nontransfemoral approaches during the study period. However, both groups experienced similarly low rate of procedural complications. Notably, no differences were observed in baseline prevalence of peripheral arterial disease, suggesting that nonfemoral access routes may have been selected due to other features such as iliofemoral tortuosity, calcification, or the presence of a horizontal aorta.[16]

Women discharged to other locations were noted to have longer intensive care unit and in-hospital stay with higher frequency of blood product transfusion. At 30 days, patients discharged to other locations had higher composite efficacy outcomes, vascular complications, bleeding, death, and stroke. However, the rates of new pacemaker requirement and stage 2 or 3 acute kidney injury needing dialysis were similar. Prior research has shown that TAVR patients with a longer duration of hospital stay have adverse short- and long-term prognosis.[17] Nontransfemoral access is associated with a greater risk of death at 30 days and at 1 year,[18] and more than 50% increase in vascular complications.[19] We noted that the incidence of bleeding and vascular complications after TAVR was significantly greater in women with non-home discharge location, who experienced these complications 2 to 3 times more frequently than women discharged home. At 1 year, the risk of composite efficacy and safety outcomes and death was significantly higher in the other location group confirming the higher risk profile and potentially unmeasured confounders associated with this group. Interestingly, the incidence of new onset atrial fibrillation through 1 year was higher in other discharge location patients, which could have resulted in a higher incidence of 1-year stroke. Moreover, the devices used in this group were mostly balloon expandable; these devices have been shown to be associated with a greater risk of stroke in a previous report.[20]

Conversely, Dodson et al.[21] noted from the Society of Thoracic Surgeons'/American College of Cardiology Transcatheter Valve Therapy (STS/ACC TVT) registry, that direct discharge home vs transfer to a skilled nursing facility did not result in significantly different rates of 30-day readmissions.[21] Nevertheless, although the median rate of home discharge in this study was 72.2%, which was similar to our study, the direct home group in Dodson et al.'s study included fewer female patients, lower rate of transfusions, and more frequent use of femoral access.[21] Although we did not collect the specific reasons for longer hospital stay in our study, this may have been largely due to nonfemoral access and higher bleeding and blood product transfusion rates but also potentially other complications including infections, multiorgan failure, decreased vitality, and social support factors resulting in need for rehabilitation and transfer to dedicated centres, particularly among elderly patients living alone. However, we did not aim to explore this in detail in the current registry design.

The implications of this analysis are that upfront patient selection processes should be meticulous to best estimate recovery of patients and necessary social support after TAVR. At all times, prohibitive-risk patients should be correctly identified to reduce the expectation of patients and families, and the added strain from long hospital stays and eventual adverse long-term prognosis.[1,22,23] Every attempt should be made to use a femoral approach with new generation devices. If femoral approach is not possible, patients should be suitably optimized for nonfemoral TAVR through management of heart failure, rhythm control, and improving renal function before TAVR. Social support is an important factor in post-TAVR outlook and independent functioning of these patients. Emotional factors in these elderly patients also influence recovery; therefore, family support and social care available after TAVR are important to be determined before undertaking the procedure. All available resources that can be mobilized should be adequately used in preparation beforehand to avoid unforeseen issues in the post-TAVR period to facilitate appropriate peri-TAVR management and discharge.[24] Prehabilitation may be of relevance in patients awaiting TAVR and may prove to be a successful approach similar to experience in cardiac surgery.[25,26]

Limitations

The registry did not aim upfront to study the socio-behavioral and economic impact of TAVR on outcomes.

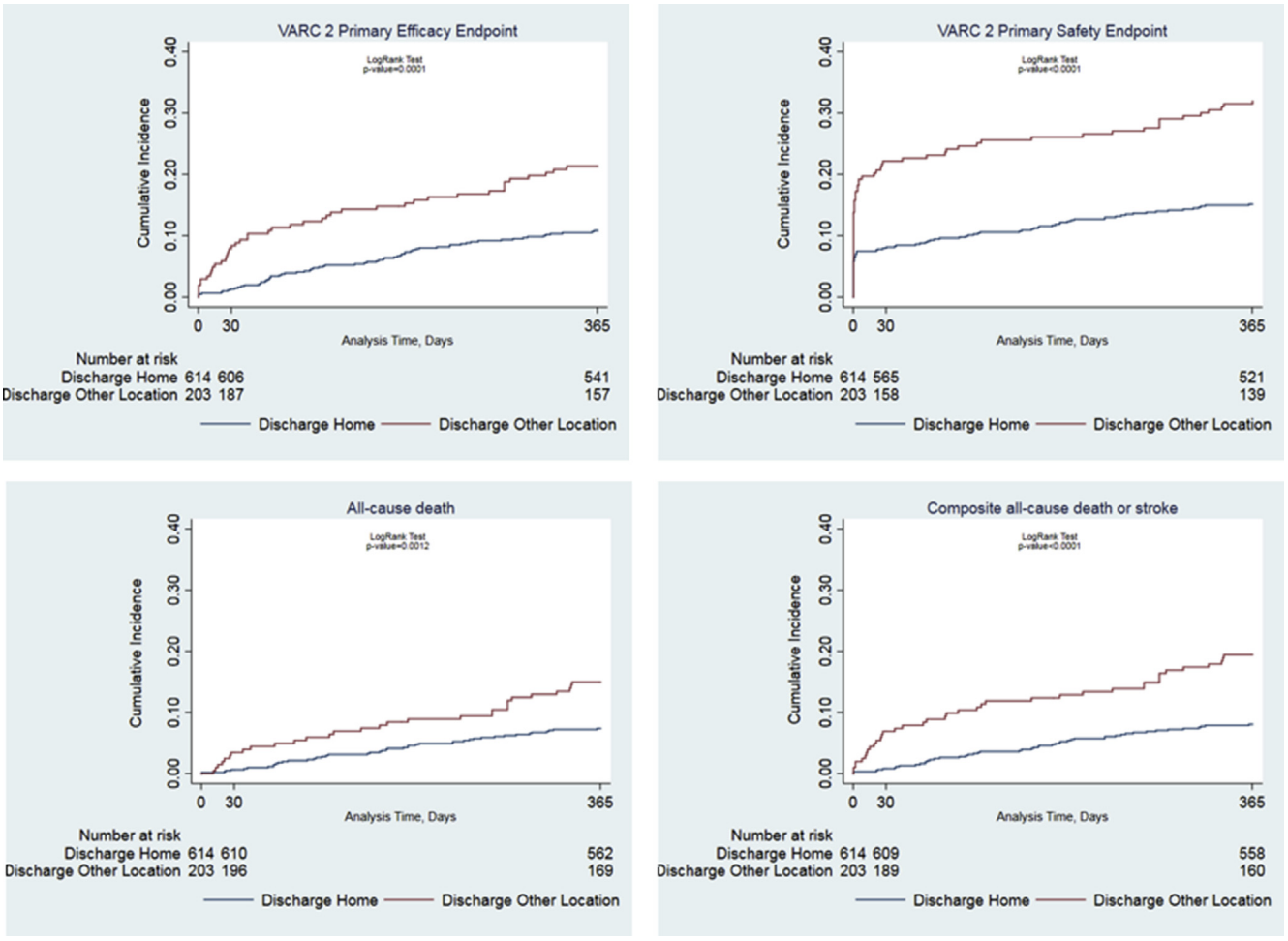

Figure 3. Cumulative incidence of 1-year clinical outcomes in patients discharged home vs other discharge locations. The figures represent the time to event occurrence of 1-year outcomes using Kaplan-Meier methods and compared using the log-rank test. VARC, Valve Academic Research Consortium.

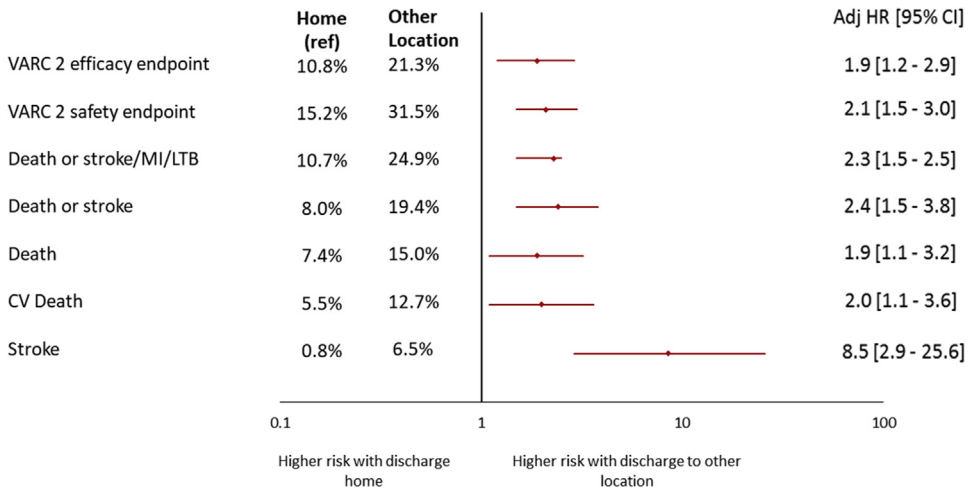

Figure 4. Incidence and adjusted risk of 1-year outcomes in patients discharged home vs other discharge locations. CI, confidence interval; CV, cardiovascular; HR, hazards ratio; LTB, life-threatening bleeding; MI, myocardial infarction; VARC, Valve Academic Research Consortium.

Majority of patients were enrolled in European centres where medical care is provided free of charge; therefore, health systems and access to insurance for medical coverage were not expected to play a role in outcomes. Family support is key to outcomes; although we tried measuring this at the times of follow-up, this may not have been accurate because we did not also collect information on the level of dependence with objective scores such as Kansas City Cardiomyopathy Questionnaire. This was a female-only registry and comparison with males was therefore not possible.

Conclusions

In women undergoing contemporary TAVR, discharge disposition significantly affects 1-year risk of outcomes even after adjustment for recorded baseline differences. This might suggest the necessity of considering additional factors beyond comorbidities in the TAVR decision-making process.

Disclosures

J. Mehilli receives lecture fees from Lilly/Daiichi Sankyo, Biotronik, Boston Scientific, Terumo, Bristol-Meyers Squibb and lecture fees and institutional research grant from Edwards Lifesciences and Abbott Vascular. A.S. Petronio receives proctorship fees from Boston Scientific and Medtronic. T. Lefèvre receives proctorship fees from Edwards Lifesciences. G. Sardella receives proctorship fees from Edwards Lifesciences and speaking fees from Direct Flow. N.M. Van Mieghem receives research grants from Boston Scientific, Edwards Lifesciences, Medtronic, St. Jude Medical, Abbott Vascular, and Claret Medical. C. Naber receives speakers fees for Edwards, Direct Flow, Medtronic, and Claret; is a minor shareholder with Claret; and is advisor to Direct Flow. M.C. Morice receives lecture fees from Abbott Vascular. R. Mehran receives research grant support from Eli Lilly/DSI, AstraZeneca, The Medicines Company, BMS, OrbusNeich; and receives consulting fees from Janssen Pharmaceuticals Inc, Medscape, Osprey Medical Inc, and Watermark Research Partners (Modest $<$ 5000/y). The rest of the authors declare that they have no relevant conflicts of interest to disclose.

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Supplementary Material

To access the supplementary material accompanying this article, visit the online version of the *Canadian Journal of Cardiology* at www.onlinecjc.ca and at https://doi.org/10.1016/j.cjca.2018.11.035.