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Original article

Early discharge following transcatheter aortic valve implantation: a feasible goal during the learning curve?

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ABSTRACT

Introduction and objectives: Although early discharge protocols after transcatheter aortic valve implantation (TAVI) have demonstrated to be safe in various studies, they are usually applied in high-experience centers. This study analyzes the length of stay of the first 100 patients undergoing TAVI in a center without on-site cardiac surgery, differentiating between very early (< 24 hours), early (24-48 hours), and late discharge (> 48 hours). Furthermore, the study evaluates the feasibility of an early discharge protocol during the team's learning curve.
Methods: We conducted a prospective observational study from April 2022 through January 2024. A preand postoperative management protocol was implemented, including assessments in the Valvular Heart Disease Clinic, admission to the cardiac surgery intensive care unit with electrocardiographic monitoring, and specific discharge criteria in full compliance with an established protocol for the management of conduction disorders. Early follow-up evaluations were performed in the outpatiently after discharge.
Results: A total of 100 patients (50% women) were included, with a mean age of 82.4 ± 5.3 years and a EuroSCORE II score of 4.38 ± 5.1%. The median length of stay was 2 days (range, 1-19). A total of 27.27% of patients were discharged in < 24 hours, 48.49% within the 24-48 hours following implantation, and 24.24% 48 hours later. The 30-day cardiovascular mortality rate was 1%. A total of 6 patients were readmitted with procedural complications within the first 30 days.
Conclusions: The implementation of a standardized care protocol allows for early and safe discharge in most patients, even during the team's learning cuve.

Keywords: TAVI. Transcatheter aortic valve implantation. Length of stay. Early discharge. Learning curve.

Alta temprana tras un implante percutáneo de válvula aórtica: ¿un reto alcanzable en plena curva de aprendizaje?

RESUMEN

Introducción y objetivos: Los protocolos de alta precoz tras el implante percutáneo de válvula aórtica (TAVI) han demostrado ser seguros en diversos estudios, aunque solo se aplican en centros con amplia experiencia. Este estudio analiza la duración de la estancia hospitalaria de los primeros 100 pacientes receptores de TAVI en un centro sin cirugía cardiaca in situ, diferenciando entre alta muy temprana (< 24 horas), temprana (24-48 horas) y tardía (> 48 horas), y evalúa la viabilidad de un protocolo de alta temprana durante la fase de aprendizaje del equipo.
Métodos: Estudio observacional prospectivo realizado entre abril de 2022 y enero de 2024. Se implementó un protocolo de cuidados prey posprocedimiento, que incluye valoración en la consulta de patología valvular, ingreso en la unidad de cuidados agudos cardiológicos con monitorización electrocardiográfica y criterios específicos para el alta según un protocolo establecido para el tratamiento de los trastornos de la conducción. Se realizó una evaluación precoz en la consulta tras el alta.

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Resultados: Se incluyó a 100 pacientes (el 50% mujeres), con una edad media de 82,4 ± 5,3 años y EuroSCORE II de 4,38 ± 5,1%. La mediana de estancia hospitalaria fue de 2 días (rango: 1-19). Se dio de alta al 27,27% de los pacientes en < 24 horas, al 48,49% en las 24-48 horas posteriores al implante y al 24,24% después de 48 horas. La mortalidad de causa cardiovascular a 30 días fue del 1%. En los primeros 30 días, 6 pacientes reingresaron por motivos relacionados con el procedimiento.
Conclusiones: La aplicación de un protocolo de cuidados estandarizado permite un alta temprana y segura en la mayoría de los pacientes, incluso durante la fase de aprendizaje del equipo.

Palabras clave: TAVI. Implante percutáneo de válvula aórtica. Estancia hospitalaria. Alta temprana. Curva de aprendizaje.

Abbreviations

CLBBB: complete left bundle branch block. **CRBBB:** complete right bundle branch block. **TAVI:** transcatheter aortic valve implantation.

INTRODUCTION

In our setting, transcatheter aortic valve implantation (TAVI) has become the treatment of choice for patients older than 75 years or with high surgical risk.[1] Despite the good results documented in various studies, the stay after the procedure remains considerably long. According to data from the Spanish registry[2], the mean length of stay is approximately 8 days. Given the increasing volume of patients, it is essential to implement protocols that optimize the length of stay and facilitate early discharge.

Experiences documented to this date on early discharge protocols after TAVI have demonstrated their safety profile.[3-13] However, there is no uniform definition of the term "early discharge," as it can range from 24 to 72 hours after the procedure.[3-13]

Most studies share common characteristics. On the one hand, they focus on procedures with a minimalist approach that favors faster patient recovery.[14,15] On the other hand, many of them exclusively include patients with favorable pre-implant conditions,[3-5,10,12] such as absence of frailty, adequate femoral access for transcatheter closure, absence of advanced conduction disorders, low-risk aortic annulus anatomy, body mass index < 35, left ventricular ejection fraction > 30%, and adequate family support. Consequently, these protocols only cover 22-55% of patients treated with TAVI.

A study conducted by a Spanish group has shown that early discharge, combined with artificial intelligence-based follow-up, is a safe strategy comparable to prolonged hospitalization in an unselected population after TAVI.[13]

Another important aspect is the type of valves used in the studies. Although the safety profile of early discharge after balloon-expandable valve implantation has been demonstrated,[6,7] evidence on self-expanding valves is scarcer, due to doubts about the occurrence of conduction disturbances in the following days. However, in recent years, experiences have been published indicating that early discharge after the implantation of this type of valve is also safe.[4,5,8,13,14]

Finally, another relevant issue in these studies is that they have been conducted in highly experienced centers.[3-13] Several analyses show that centers with a higher volume of procedures and more accumulated experience have lower complication rates and better overall results,[16,17] which may translate into greater confidence in adopting early discharge practices.

It seems clear that reducing the length of stay through the implementation of early discharge protocols is a strategy that has demonstrated its feasibility in experienced centers. However, its application in those starting TAVI programs requires additional studies that ensure comparable results in terms of safety. Therefore, the objective of our study is to evaluate the length of stay of the first 100 patients treated with TAVI in our hospital (very early discharge: < 24 hours; early discharge: 24-48 hours; late discharge: > 48 hours) and determine the feasibility of establishing an early discharge protocol during the team's learning curve.

METHODS

Patient selection and follow-up

We conducted a prospective, single-center registry that consecutively included all patients with severe symptomatic aortic stenosis who underwent TAVI in a center without on-site cardiac surgery, from the beginning of the program. The reference cardiac surgery department is located in a different center 2 km away.

The patients' baseline characteristics, pre- and postoperative electrocardiographic and echocardiographic findings, the procedural characteristics, and the 30-day and 1-year clinical outcomes were recorded. The registry has been approved by *Hospital Universitario Nuestra Señora de Candelaria* ethics committee. Relevant informed consents were obtained.

Pre- and postoperative care protocol

We developed a pre- and postoperative care protocol to standardize patient management (figure 1), in such a way that during the week prior to implantation, a cardiologist and a nurse specialized in TAVI jointly assess patients in the monographic valvular heart disease clinic. During this visit, additional tests are reviewed, the patient and their family are briefed on the procedure and possible complications, the informed consent form and a leaflet with relevant information are provided (drug management, how to proceed on implantation day, contact telephone number, etc.). Patients receive a call from nursing staff 48 hours prior to the intervention to remind them of the instructions.

On the morning of the procedure, patients go to the interventional cardiology unit of our center, where a venous line is established, an electrocardiogram is performed, and prophylactic antibiotics are administered. After implantation, they are admitted to the acute cardiac care unit with electrocardiographic monitoring. The next day, the absence of complications is ruled out, an electrocardiogram

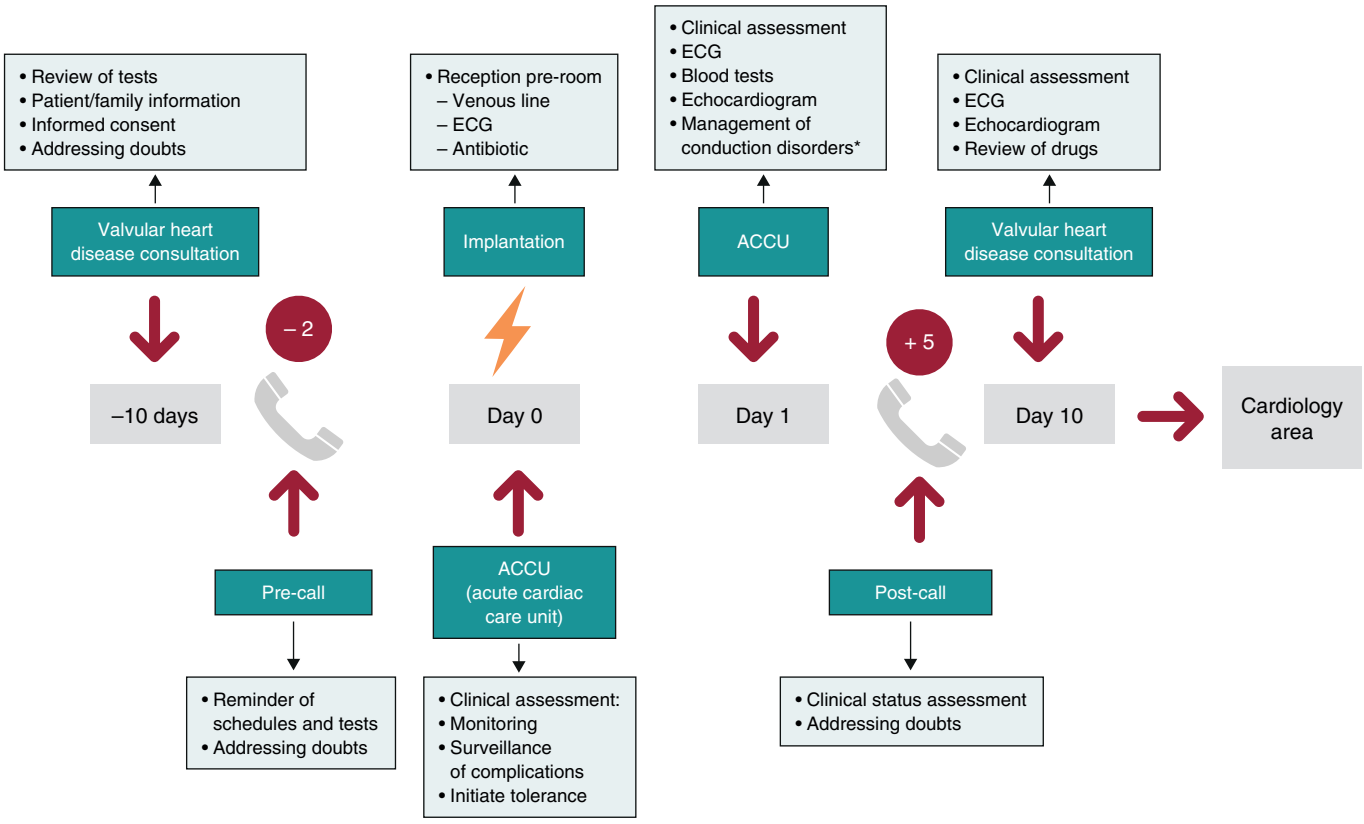

Figure 1. Pre- and postoperative care protocol for transcatheter aortic valve implantation. ECG, electrocardiogram.

and a transthoracic echocardiogram are performed, and the discharge decision is made according to the protocol for the approach and treatment of conduction disorders by Rodés-Cabau J et al.[18] adapted to our center (figure 2).

During follow-up, a telephone consultation is conducted 48 hours after discharge to rule out any complications, and a face-to-face consultation with electrocardiogram and transthoracic echocardiogram is performed 10 days later. If progress is adequate, follow-up continues in general cardiology clinics. The care protocol and the algorithm for the treatment of conduction disorders are showin in figure 1 and figure 2, respectively.

Procedural characteristics

During the team's learning curve, a "mixed" approach was selected. Procedures were performed under general anesthesia. Regarding vascular access, transcatheter transfemoral primary access and closure with double Prostyle (Abbott Vascular, United States) and AngioSeal (Terumo) were prioritized; the radial route was used as secondary access. Pacing was performed with a balloon-tipped electrocatheter via jugular venous access. Urinary catheterization was omitted. The self-expanding Evolut R/PRO+ (Medtronic, United States and Ireland) and ACURATE neo2 (Boston Scientific, United States) valve were implanted. Transthoracic echocardiography was used for postoperative monitoring.

Endpoints

The endpoint of this study is to analyze the length of stay of the first 100 patients undergoing TAVI in our center, differentiating between very early (< 24 hours), early (24-48 hours), and late discharge (> 48 hours) and evaluate the possibility of establishing an early discharge protocol during the team's learning curve.

In addition, we aim to evaluate clinical outcomes according to the VARC-3 standardized definitions,[19] including cardiovascular and non-cardiovascular mortality at 30 days and between 30 days and 1 year, procedural or cardiovascular-related rehospitalizations at 30 days, need for pacemaker implantation in the same period, and rate of neurological events, bleeding complications > BARC 3a, major vascular complications, and cardiac structural complications.

Statistical analysis

Qualitative variables are expressed as absolute frequency and percentage, and the continuous ones as mean and standard deviation.

RESULTS

The first 100 patients treated with TAVI in a tertiary referral center without an on-site cardiac surgery department were prospectively included from April 2022 through January 2024.

The patients' baseline characteristics

The patients' baseline characteristics are shown in table 1. Of note, 50% were men, with a mean age of 82.4 ± 5.3 years. The STS score was 4.3 ± 5.1% and the EuroSCORE II score, 4.38 ± 5.1%. The main

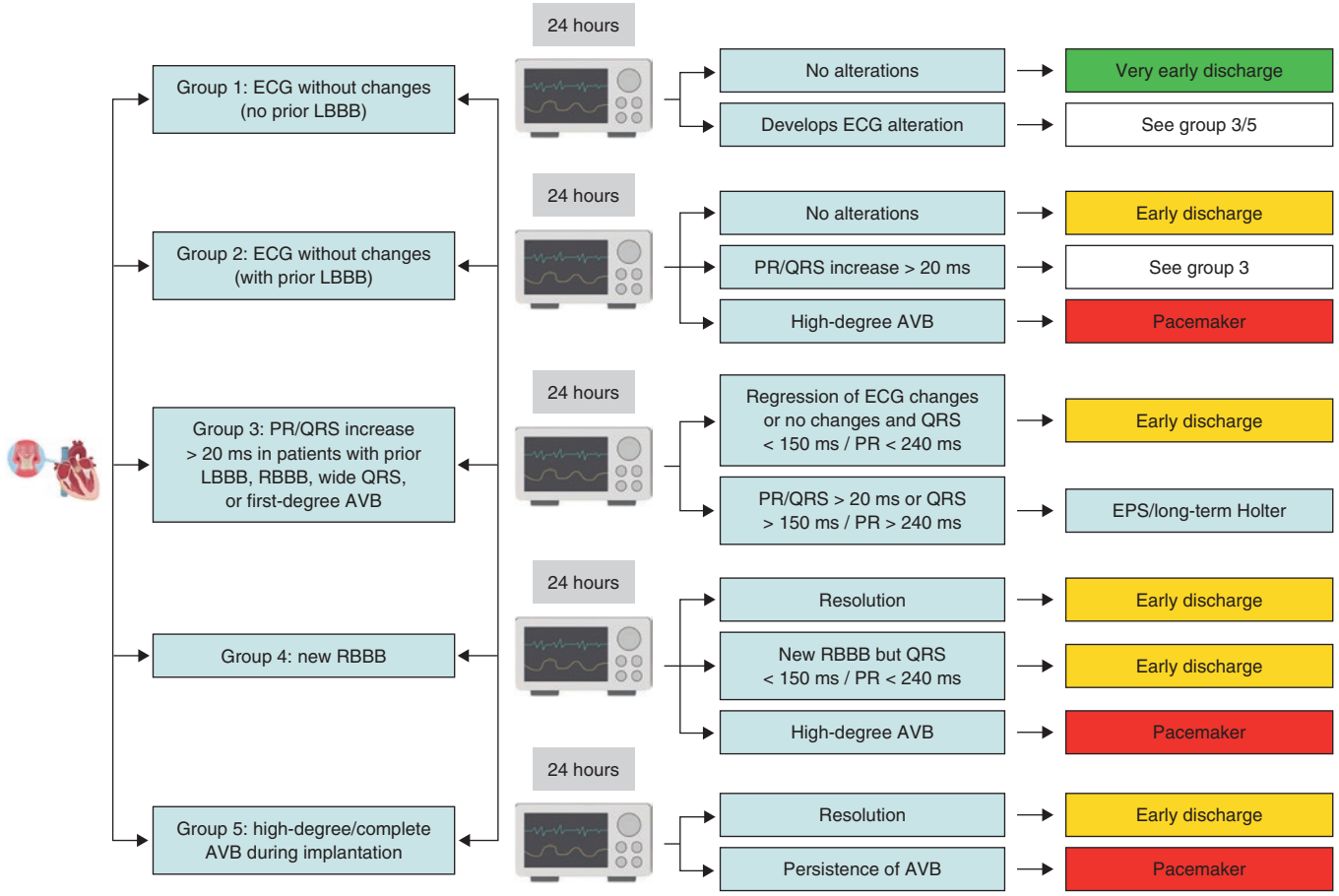

Figure 2. Protocol for the management of conduction disorders after transcatheter aortic valve implantation. Very early discharge: < 24 hours; early discharge: 24-48 hours. AVB, atrioventricular block; ECG, electrocardiogram; EPS, electrophysiological study; LBBB: left bundle branch block; RBBB, right bundle branch block.

indication for implantation was age older than 75 years in 96% and high surgical risk in patients younger than 75 years in 4%. Regarding baseline conduction disorders, 10% of patients had complete left bundle branch block, 11%, complete right bundle branch block, and 12% a previously implanted pacemaker.

Procedural characteristics and perioperative results

Procedural characteristics and perioperative results are summarized in table 2. Procedures were performed under general anesthesia, and all patients were extubated in the operating room. Access was transcatheter transfemoral in 95% of patients, with closure using double Prostyle (Abbott Vascular, United States) and AngioSeal (Terumo, Japan). A total of 5% of these patients required surgical access by the vascular surgery service (2%, femoral; 3%, axillary). Second access was radial in 98% of cases.

A total of 24 proctored cases were performed. Valve implantation was successful in 100% of cases. A total of 98 procedures were performed on native aortic valves (95, trileaflet; 3, bicuspid) and 2 on degenerated surgical bioprostheses using the chimney stent technique. Self-expanding valves were implanted (87%, Evolut R/PRO+; 13%, ACURATE neo2).

The immediate outcome was monitored with transthoracic echocardiography. More than moderate residual aortic regurgitation occurred in only 2 patients. There were no annular ruptures, aortic complications, coronary artery occlusions, device embolizations, or need for conversion to surgery. No patients died during the procedure.

Mortality and complications after TAVI

Mortality and complications after TAVI are shown in table 3. The 30-day cardiovascular mortality rate was 1% (1 patient who died during hospitalization due to heart failure complicated by a respiratory sepsis). In the follow-up after discharge, 2 deaths due to non-cardiovascular causes were recorded: 1 patient died from aspiration pneumonia at 6 months and another due to complications derived from colon cancer 9 months after implantation.

Within the first 30 days, 6 patients required admission for procedural or cardiovascular-related causes. The reason for admission was infection in 3 patients: a wound infection in a patient who underwent surgical femoral access, an early infective endocarditis that had a good outcome with optimal medical therapy, and a pacemaker pocket infection that required device explantation and contralateral implantation. One patient was admitted with heart failure for developing rapid atrial fibrillation. Two patients were admitted for syncope; one had a PR interval of 350 ms and the other complete atrioventricular block. Both underwent permanent pacemaker implantation.

The rate of major vascular complications was 4%: 3 patients presented stenosis or dissection of the common femoral artery

Table 1. Patient characteristics and indication for transcatheter aortic valve implantation

Variables	Values
Baseline characteristics	
Age, years	82.4 ± 5.36
Sex (male/female)	50/50
Cardiovascular risk factors	
Hypertension	73 (73)
Diabetes mellitus	43 (43)
Dyslipidemia	61 (61)
Active smoking	16 (16)
Past medical history	
Coronary artery disease	37 (37)
Previous cardiac surgery	13 (13)
Atrial fibrillation	34 (34)
Heart failure	31 (31)
Chronic kidney disease	44 (44)
Previous permanent pacemaker	12 (12)
Previous LBBB	10 (10)
Previous RBBB	11 (11)
Baseline echocardiogram	
LVEF, %	58.8 ± 10.1
Peak gradient, mmHg	71.4 ± 15.8
Mean gradient, mmHg	44.8 ± 10.8
Aortic valve area, cm^2	0.75 ± 0.139
Aortic regurgitation	36 (36)
Bicuspid aortic valve	3 (3)
Surgical risk	
EuroSCORE II	4.32 ± 5.15
STS score	4.38 ± 3.34
Indication for implantation	
Age > 75 years	96 (96)
High surgical risk in patients < 75 years	4 (4)

LBBB, left bundle branch block; LVEF, left ventricular ejection fraction; RBBB, right bundle branch block; STS, Society of Thoracic Surgeons.
Unless otherwise indicated, data are expressed as frequency and percentage (n, %) or mean ± standard deviation.

requiring stent implantation during the same procedure; furthermore, a femoral pseudoaneurysm was detected in 1 patient and was surgically repaired. One case of BARC > 3a bleeding complication was detected; the patient required transfusion of 2 packed red blood cell concentrates due to lower GI bleeding.

One patient had a stroke at 24 hours. The need for permanent pacemaker implantation was 12.5% within the first 30 days. The delay for permanent pacemaker implantation once the indication was established was < 48 hours.

Table 2. Procedural characteristics and perioperative outcomes

Procedural characteristics and outcomes	Values
Characteristics	
Proctored (yes/no)	24/76
Vascular access	
Transcatheter femoral	95 (95)
Surgical femoral	2 (2)
Surgical axillary	3 (3)
Native valve	98 (98)
Valve-in-valve	2 (2)
Predilation	88 (88)
Postdilation	22 (22)
Type of valve	
Evolut R/PRO+, Medtronic	87 (87)
ACURATE neo2, Boston Scientific	13 (13)
Perioperative outcomes	
Intraoperative mortality	0 (0)
Post-implantation gradient > 20 mmHg	0 (0)
Aortic regurgitation > grade II	2 (2)
Aortic annulus rupture	0 (0)
Aortic dissection	0 (0)
Coronary artery occlusion	0 (0)
Device embolization	0 (0)
Conversion to surgery	0 (0)

Data are expressed as frequency and percentage (n, %).

Table 3. Complications and mortality after transcatheter aortic valve implantation

Complications and Mortality	n (%)
Transient LBBB	26 (33)
Persistent LBBB at discharge	6 (7.6)
Pacemaker implantation at 30 days	11 (12.5)
Stroke	1 (1)
Bleeding complications > BARC 3[a]	1 (1)
Major vascular complications	4 (4)
Cardiovascular rehospitalization at 30 days	6 (6)
Cardiovascular mortality at 30 days	1 (1)
Non-cardiovascular mortality at 30 days	0 (0)
Cardiovascular mortality from 30 days to 1 year	0 (0)
Non-cardiovascular mortality from 30 days to 1 year	2 (2)

BARC: Bleeding Academy Research Consortium scale; LBBB: left bundle branch block.
[a] Data are expressed in numbers and percentages (n, %).

Table 4. Length of stay

Length of stay	Time
Length of stay, days	2 (1-19)
Very early discharge < 24 hours	27 (27.27)
Early discharge 24-48 hours	48 (48.49)
Late discharge > 48 hours	24 (24.24)

ME: median; n: number.
Data are expressed in days and median (interquartile range) or in number and percentage (n, %).

Length of stay

The pre-specified care protocol was implemented in all patients (figure 1 and figure 2). As a result, the median length of stay was 2 days (range, 1-19) for all patients (table 4). Regarding time to discharge (figure 3), 27 patients (27.27%) were discharged within the first 24 hours (very early discharge), 48 (48.49%) between 24 and 48 hours after implantation (early discharge), while 24 patients (24.24%) had to be hospitalized for more than 48 hours (late discharge). Late discharges corresponded to 8 patients whose TAVI was performed during admission for heart failure or cardiogenic shock, 10 patients who had pre-existing conduction disorders (mainly first-degree atrioventricular block or complete right bundle branch block) or who developed them after implantation and required prolonged electrocardiographic monitoring, 2 patients who underwent surgical femoral access, 2 patients with major vascular complications, 1 patient who had a stroke at 24 hours, and 1 patient who developed bacteremia due to *Streptococcus mitis*.

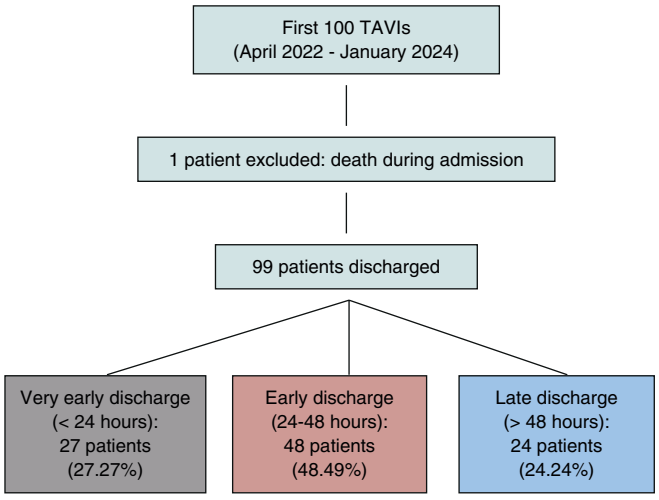

Figure 3. Length of stay of the first 100 TAVI patients. TAVI, transcatheter aortic valve implantation.

DISCUSSION

The main findings of our study are *a)* it is feasible to establish a protocol that favors the early discharge of patients during the medical team's learning curve; *b)* approximately 75% of patients achieve early discharge (< 48 hours); and *c)* it is a safe strategy associated with a low rate of adverse events at 30 days.

The progressive increase in the number of patients we will be facing in the coming years makes it essential to establish protocols that optimize the length of stay and allow for efficient use of resources.

Several experiences can be found in the literature confirming that early discharge protocols after TAVI are safe. The main problems they present are the lack of a standardized definition of early discharge, which can vary from 24 to 72 hours,[3-13] and that most studies on early discharge agree on including patients with favorable anatomical characteristics,[3-5,10,12] such as adequate femoral access for transcatheter closure, absence of advanced conduction disorders, low-risk aortic annulus anatomy, body mass index < 35, and left ventricular ejection fraction > 30%; in addition, they exclude patients with factors that could prolong the length of stay, such as frailty or lack of family support. Following these criteria, only 59% of our patients would have been eligible for an early discharge program, yet we were able to discharge 75% of the patients within the first 48 hours. In our series, the median length of stay for outpatients with the favorable characteristics described above is 2 days (1-10), and that of outpatients who did not meet favorable criteria is 2 days (1-18), while the length of stay of the 8 patients undergoing TAVI during hospitalization for decompensated heart failure or cardiogenic shock is 10.5 days (1-30). In this regard, the experience of Herrero et al.[13] is noteworthy, who demonstrated in their study that most patients (73%) in an unselected population can be safely discharged within the first 24-48 hours.

The minimalist approach[14,15] is another key aspect that has been shown to favor early discharge. This approach is especially suitable when conducted by experienced teams and applied to collaborative, hemodynamically stable patients without anatomical characteristics involving a higher risk of complications. Its implementation should be progressive, so that the safety profile of the procedure is guaranteed as the fundamental priority. We opted to start the TAVI program with a "mixed" approach with general anesthesia, mainly femoral or radial access, pacing with a transvenous pacemaker, and monitoring with transthoracic echocardiography until the team overcame the learning curve. All patients were successfully extubated in the operating room. Therefore, we believe that this type of approach did not cause any delays in patient discharge. Once the first 100 cases have been completed, we are transitioning towards a fully minimalist procedure due to the benefits this entails for the patient.

The safety profile of early discharge after the implantation of self-expanding valves has been widely discussed[4,5,8,13,14], due to the increased risk of developing cardiac conduction disorders. In our study, all patients received a self-expanding valve. The algorithm by Rodés-Cabau et al.[18] was applied to determine the duration of electrocardiographic monitoring and manage conduction disorders. The need for permanent pacemaker implantation was confirmed in 12.5% of cases within the first 30 days. Only 2 patients required readmission after discharge due to advanced conduction disorders requiring pacemaker implantation.

In addition, it is important to have a close follow-up system that allows for the early detection of post-discharge complications and ensures continuity of care. To this end, our patients receive a telephone consultation 48 hours after discharge, and a face-to-face consultation with electrocardiograms and echocardiograms being performed at 10 days. They also have a telephone number to contact the team during working hours. Undoubtedly, this is a system that takes human and economic resources. Experiences have been reported in which the implementation of a virtual voice assistant facilitates the detection of complications, thus demonstrating the effectiveness of this system,[13] which should be considered the standard we should look for in clinical practice.

Reducing the length of stay after TAVI requires a real commitment from the heart team to the implementation and adherence to an early discharge protocol. The BENCHMARK study[20] showed that adherence to an 8-point structured protocol allows for shorter lengths of stay of approximately 2 days. The key aspects identified in this protocol include educating the health care team, a clear definition of discharge criteria, a structured decision algorithm to assess the need for pacemaker implantation, echocardiographic or angiographic follow-up of the puncture site, early patient mobilization, patient and family education, and anticipated discharge planning from admission. In our own experience, the role of a cardiologist coordinating the TAVI program, along with close collaboration with key units and services, such as acute cardiac care, imaging, electrophysiology, anesthesiology, vascular surgery, and radiology, has enabled the effective implementation of these strategies. This approach has facilitated the consolidation of an early discharge protocol from the start of the program.

Limitations

Our study has multiple limitations that may affect result extrapolation. On the one hand, this was a study of observational design conducted in a single center and with a small sample size; additionally, a total of 24 cases were performed under supervision. On the other hand, only self-expanding valves were used, meaning that results cannot be generalized to other types of valves.

CONCLUSIONS

During the team's learning curve, the application of a standardized care protocol allows for early and safe discharge after TAVI in most patients in an unselected population.

FUNDING

None declared.

ETHICAL CONSIDERATIONS

Approval was obtained from *Hospital Universitario Nuestra Señora de Candelaria* ethics committee. Informed consents are available. The SAGER guidelines regarding potential sex and gender biases have been followed.

STATEMENT ON THE USE OF ARTIFICIAL INTELLIGENCE

Artificial intelligence has not been used for the development of the study.

AUTHORS' CONTRIBUTIONS

R. Pimienta González and A. Quijada Fumero participated developing the protocol, collecting data, and drafting the manuscript. All authors participated in the study design, critically reviewed the text, and approved its final version.

CONFLICTS OF INTEREST

None declared.

WHAT IS KNOWN ABOUT THE TOPIC?

- The constant increase in the number of TAVIs being performed has created the need to establish protocols that reduce the length of stay.
- Several studies have shown that early discharge protocols are safe, as long as they are implemented in experienced centers.
- However, it is still unknown whether it is feasible to apply an early discharge protocol from the beginning of a TAVI program.

WHAT DOES THIS STUDY ADD?

- The implementation of a care protocol adapted to the specific characteristics of each center allows for early and safe discharge of most patients after TAVI, even during the team's learning curve.

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