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**Research Article**

# Nursing-Guided Pre-Procedural Preparation In Patients Undergoing Transcatheter Aortic Valve Replacement

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## Abstract

**Background:** Transcatheter Aortic Valve Replacement (TAVR) has become the treatment of choice for many patients with severe symptomatic aortic stenosis (AS). For TAVR candidate a multidisciplinary evaluation is necessary where nursing currently has an anecdotal participation. Our objective was the development and implementation of a TAVR program nurse led including a pre-TAVR assessment protocol for the patient and caregiver based in patient-centered approach. **Methods**: A multidisciplinary working group was created to develop the necessary contents for the TAVR nurse program and the TAVR pre-implantation nursing guide. A retrospective analysis of the preliminary single-center experience on pre-implantation assessment was performed. **Results:** A Pre-TAVR nurse clinic was launched to be carried out approximately 7-15 days before the intervention, focusing on training and education and a global patient assessment on geriatric features, frailty, cognitive impairment, dependence, quality of life and social support. 40 patients were evaluated in the preprocedural outclinic and subsequently the interventions were performed from March 2022 to July 2022. Regarding patient satisfaction with the pre-TAVR nurse consultation a mean score of 9,8 points was achieved for all items evaluated. **Conclusion:** Implementing a TAVR nurse program with a patient-centered approach is feasible and could help to improve the patient preparation, education and coaching, maintain continuity of care, and increase patient satisfaction throughout the TAVR process.

## Introduction

Severe aortic stenosis (AS) is the most common primary heart valvular disease in developed countries. Its growth is related to a higher life expectancy and increasing ageing of the population [1-3]. Its estimated prevalence is significant, being 2.5% in the general population, reaching up to 7% in the population over 65 and to 13% in those over 75 [4-5]. Patients might remain asymptomatic for many years, but once symptoms appear, the associated 3-year mortality rate without intervention can reach up to 50% [6-7]. In the last two decades, Transcatheter Aortic Valve Replacement (TAVR) has transformed the management of severe symptomatic AS [8], positioning as a less invasive alternative to traditional surgical (SAVR) with equivalent or even better outcomes [3].

TAVR was started as an alternative in inoperable or high surgical risk patients, but this therapeutic option has grown very rapidly during last years. This growth and the associated success are the result of technological progress, increased operator expertise, improved safety, and the reduction of intraprocedural complications. The combination of these factors allowed for the expansion of indications including lower risk patients in whom TAVR confirmed favorable outcomes compared to SAVR [3-8]. This represents a paradigm shift in the treatment of valvular heart disease, with a transition to minimally invasive procedures which allow to reduce the in-hospital length of stay, to optimize the use of healthcare resources and to improve patient health outcomes without increasing mortality and complications [9-12].

For TAVR candidate a multidisciplinary evaluation is necessary where nursing currently has an anecdotal participation. It is necessary to develop TAVR programs that place the patient at the very center of the process and ensure multidisciplinary decision-making with the nurse playing a key role in case management and preparation before intervention (which include undertaking the necessary tests and providing proper information and education resources to the patient and its family), to ensure an adequate adherence to the treatment and faster recovery. Patient education and coaching provided by the nurse staff helps to improve patient satisfaction, anticipate and prevent complications, plan an early discharge, and maintain continuity of care [4,13-16].

We aimed to develop and implement a process led by nursing in patients undergoing TARV including a pre-TAVR assessment protocol for the patient and caregiver to improve their preparation and knowledge and to help reduce patient anxiety, complications, and in-hospital length of stay.

## Methods

A multidisciplinary working group was created, consisting of interventional, clinical, and imaging cardiologists together with the team of nurses familiar with the TAVR procedure (TAVR nurse). The team also included a process engineer acting as a facilitator and ensuring that the team worked applying lean management methodology. The purpose of this team was to reach a consensus on the essential aspects to be included in the nursing TAVR assessment protocol and, to subsequently validate and implement the protocol. To this end, regular team meetings have been scheduled. A protocol called TAVR nurse was developed for use in our center, including prior nursing assessment, during admission and follow-up.

An exhaustive literature review was conducted which, combined with the knowledge and experience of the multidisciplinary team, was key to develop the necessary contents for the TAVR pre-implantation nursing guide (focusing on description and management of the disease, the TAVR procedure, the patient's pathway and the discharge care plan).

In our center, the pre-TAVR assessment includes an angio-computed tomography (CT) of the aorta and the feasibility of vascular access (transfemoral choice), the size of the aortic annulus for prosthesis selection, and the coronary arteries by non-invasive coronary angiography. Elective TAVR is performed according to the Hospital protocol with admission of the patient on the same day of the procedure at the Cardiac Day Care Unit. TAVR is then performed under conscious sedation in cases of transfemoral access or under general anesthesia in other types of access (subclavian, transapical or transcava...). After the procedure, the patient is transferred to the Intensive Cardiac Care Unit (ICCU) for a minimum of 24 hours, with a total length of stay of 2-4 days depending on the risk of atrioventricular (AV) block and in the absence of major complications.

Once the TAVR nurse program was developed and implemented, we performed a retrospective analysis of the preliminary single-center experience on pre-implantation assessment of TAVR by nurses in patients with severe AS with indication for intervention and accepted for TAVR by the Heart Team. The data collection was conformed to the principles outlined in the Declaration of Helsinki and were properly anonymized.

Statistical analysis was performed using the IBM SPSS Statistics for Windows package, version 22 (IBM Corp., Armonk, N.Y., USA). The qualitative variables were expressed as absolute frequency (n) and percentage (%) and the continuous ones by mean and standard deviation (SD) or median and interquartile range (IQR) depending on the distribution according to the normality.

## Results

### TAVR nurse protocol

As a result, a protocol for nursing assessment throughout the whole TAVR process was established, together with the development of specific material.

Once the indication for aortic valve intervention is established and is decided by the Heart team that the patient is candidate for TAVR, a group of nurses, experienced in Cardiology and with experience in the different phases of TAVR, assess patients in different phases (pre-TAVR consultation, during hospitalization and post-TAVR consultation follow-up), in parallel with the established medical follow-up.

### Pre-TAVR nurse consultation

A face-to-face clinical assessment by a nurse in a outclinic is carried out approximately 7-15 days before the intervention, which could be adapted depending on the urgency of the procedure. The consultation has a duration of 45 minutes and pursues three main objectives, for which different specific materials were elaborated:

### Information about the disease and the TAVR procedure

An educational guide was developed to facilitate the retention of information, including oral and written materials consisting of:

- Slide show oriented to health education which includes different aspects: definition of AS, cardiac anatomy, most common symptoms of the disease and TAVR procedure (accesses, anesthesia/conscious sedation, prosthesis, explanation of the technique). Also, it includes a virtual tour of all the units of the patient pathway from admission to discharge: Day care unit (for the preparation before the procedure), catheterization laboratory, ICCU and cardiology ward. (Figure 1)

- Brochure for handing out to patients and caregivers which includes information about the admission process, the care plan provided in each unit, important reminders for the day of the procedure (fasting, medication, etc.) and contact details to resolve doubts or ask questions. (Figure 2)



**Figure 1:** TAVR patient education slides presentation;Slides presentation showed in pre-TAVR nurse consultation; TAVR= Transcatheter aortic valve aortic replacement; Sources: http://cardiosaudeferrol.com, Edwards Lifes science, Abbott laboratories, Medtronic, Boston scientific, Virgen del Rocio Hospital.
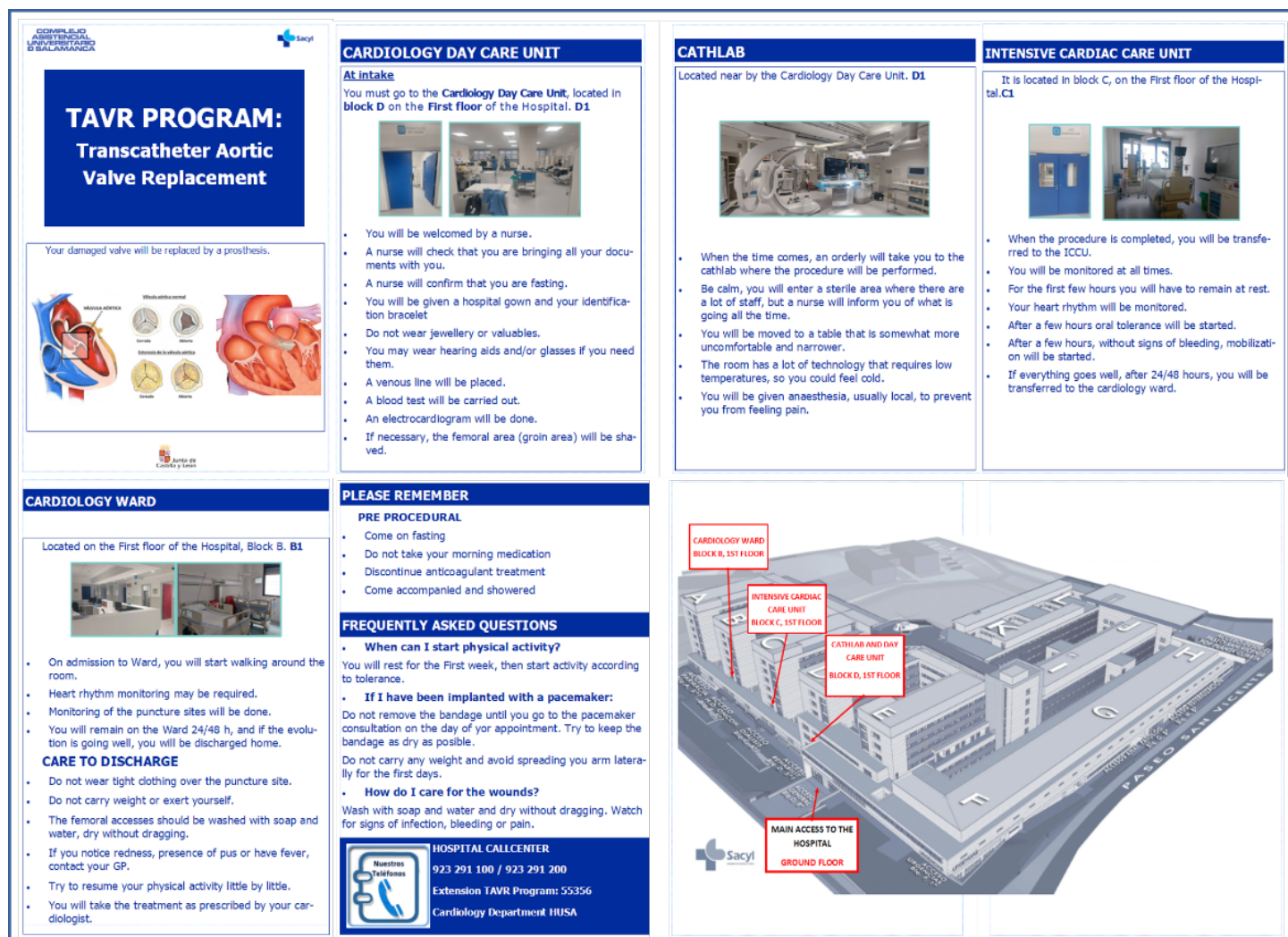
**Figure 2:** Informative handout Informative brochure delivered to the patient and caregiver in pre-TAVR nurse consultation; GP= General practitioner; HUSA= Hospital ; Universitario de Salamanca; ICCU= Intensive cardiac care unit; TAVR= Transcatheter aortic valve aortic replacement.

*Assessment of medical history and complementary pre-TAVR tests*

In order to detect possible sources of complications related to the procedure, it was decided to perform a preliminary evaluation of the patient's medical history, checking important aspects for the procedure: allergies (medication, iodated contrast, etc.), blood tests (hemogram, renal function, etc.), medication review, paying special attention to antithrombotic treatment (anticoagulation and antiplatelet therapy) to specify, according to our protocol, when and how medication should be discontinued, check whether the necessary tests have been performed or are still pending (echocardiogram, pre-TAVR CT) and depending on the accesses selected, a pre-anaesthetic examination before the procedure could be required (in cases of subclavian, transapical or transcava access).

*Global patient assessment*

Clinical, physical, psychological and psychosocial aspects were included. More specifically, the nursing assessment focused on geriatric features, frailty, cognitive impairment, dependence, quality of life and social support. These issues may be a key to the acceptance or rejection of the TAVR procedure, can be predictors of complications or longer admissions, or may help to identify patients who are eligible for cardiac rehabilitation programs once the TAVR has been implanted.

For our TAVR nurse protocol, based on the recommendations of the 2021 European guidelines AS [17], we selected the following validated scales:

- The New York Heart Association (NYHA) functional classification is a grading system for heart failure, it focuses on exercise capacity and symptomatic status. Score range from I to IV level, with the higher scores indicating poor function.

- KATZ Dependency assessment Index analyzes the activities in daily living (ADLs) scores range from 0 to 6 (bathing, dressing, using the toilet, transferring between bed and chair, maintaining continence, and feeding), with higher scores indicating better function [18].

- The Gijon Socio-family scale (modified version) analyzes social determinants of health. This instrument evaluates five components of risk situations and social problems, including family, economic status, housing, social relationships and support networks. Score ≥10 indicates high social risk [19].

- Mini mental State Examination (MMSE) to evaluate cognitive functions, with scores from 0 to 30, the higher punctuations indicated better cognitive performance [20].

- Frailty scale FRAIL evaluates 5 items: Fatigue, Resistance, Ambulation, Illnesses and Loss of Weight. Score ≥3 indicate frail patient, 1-2 prefrail and 0 no frail [21].

- Quality of life questionnaire Short Form Health Survey 36 (SF-36) is widely used in cardiac patients. There are shorter versions, such as SF-12, but this brevity can come at the cost of losing valuable information, so we selected for the longer version SF 36. The items in SF-36 are divided into nine different domains with overall physical and mental health component summary scores. Domains are physical functioning, role limitations physical, bodily pain, social functioning, general mental health, role limitations emotional, vitality and general health and health transition. Each domain score from 0 to 100, and higher score translates higher perception about patient quality of life in each domain, being able to calculate an overall percentage about the general quality of life [22].

In addition, considering the importance that patients give to being informed beforehand and feeling accompanied and engaged in their healthcare plan, an additional own local questionnaire was designed ad hoc, to assess patient expectations of the TAVR procedure and to evaluate patient satisfaction with the pre-TAVR nurse consultation, (Figure 3) reflects this scale.

*TAVR nurse assessment during whole admission*

We established by protocol that TAVR nurse would visit the patient in each of the units to which is admitted: day care unit, cathlab, ICCU and cardiology hospitalization ward, in order to follow patient's evolution, be the point of contact between family and patient, resolve doubts and establish the care plan for early discharge to be delivered at the patient's own home.

*TAVR nurse follow-up consultation*

Finally, a post-procedure nursing outclnic was established, which occurs approximately 30 days after TAVI implantation. In those patients who have had some complications or who do not have socio-familial support (selected patients), the follow-up consultation is carried out after 7 days, in order to avoid readmissions or major complications. During this consultation, the nurse performs again a comprehensive assessment, including again quality-of-life by SF-36 and NYHA functional class evaluation. In addition, in our protocol, we have added an ad hoc questionnaire on patient experience and patient-perceived quality during the TAVR process to allow for feedback and continuous improvement .summarizes the TAVR protocol throughout the entire process Figure 4



**Figure 3:** Satisfaction and expectations questionnaire pre TAVR ; Local questionnaire designed to assess patient expectations of the TAVR procedure and to evaluate patient satisfaction with the pre-TAVR nurse consultation; TAVR= Transcatheter aortic valve aortic replacement.
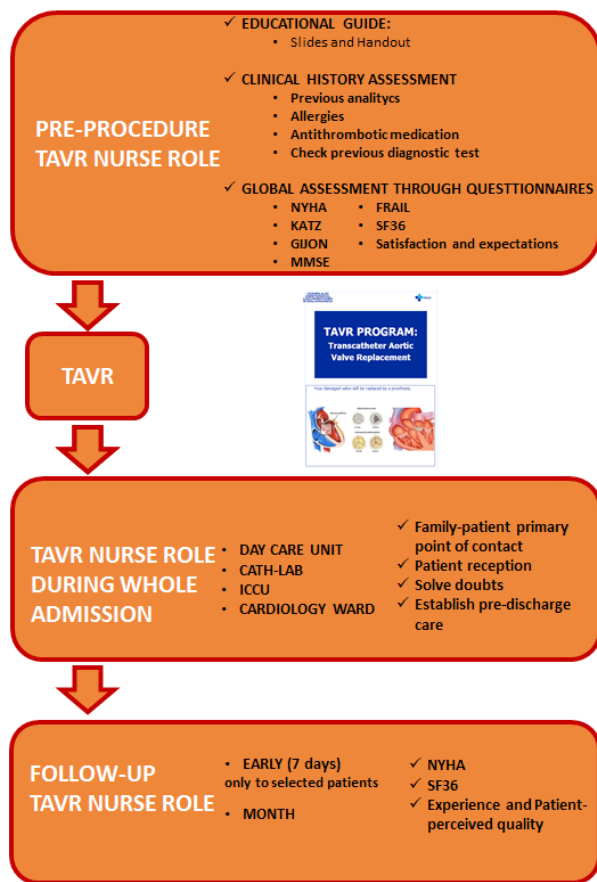
**Figure 4:** Nursing assessment protocol in patients undergoing TAVR (TAVR nurse program) Nurse role during each phase in the TAVR program. FRAIL; Frailty scale; GIJON Modified= Gijon Socio- family scale (modified version); ICCU= intensive cardiovascular care unit; KATZ= Dependency assessment Index analyzes the activities in daily living (ADLs); MMSE= Mini mental state questionnaire; NYHA= The New York Heart Association functional classification; SF-36= Short Form Health Survey 36 questionnaire (quality of life); TAVR= Transcatheter aortic valve aortic replacement.

## Results on nursing guided pre-TAVR preparation in patients undergoing transcatheter aortic valve replacement

40 patients have been already evaluated in TAVR nurse preprocedural outclinic, and subsequently the interventions performed from March 2022 to July 2022.

The pre-TAVR evaluation was carried out a median of 15 [26] days before the intervention.

The characteristics of the pre-TAVI evaluation and the TAVR admission data are summarized in (Table 1). The data reflects that our sample is an ageing population with multiple cardiovascular risk factors. Most patients present preserved left ventricular ejection fraction with a NYHA functional class II-III.

The preprocedural TAVR scores used reflect a population with virtually no social risk according to the Modified Gijon social assessment scale. In terms of dependence and frailty, 20% showed some grade of dependence analyzed by the Katz Index (<6 points score), and half of our sample were pre-frail according to the FRAIL scale, with 10% of them being frail. 10% showed signs of cognitive impairment according to the MMSE scale. According to the SF-36 quality of life questionnaire, patients showed poor quality of life with a median of 46%. With regard to the patient's expectations about TAVR, most of them reflected as the main objective not to become fatigued or to become less fatigued. Regarding patient satisfaction with the pre-TAVR nurse consultation, a mean score greater than 9.8 was obtained for all the items evaluated (table 1).

TAVR was performed through femoral access and with conscious sedation in 97.5% of the cases. 1 patient required endotracheal intubation due to a complication (cardiac tamponade managed with pericardial drainage without further complications). After TAVR, the results showed successful implantation or mild aortic regurgitation in 90% of patients. 15% of the patients underwent percutaneous coronary revascularization simultaneously. Complications are also shown in Table 1, with vascular complications being the most frequent, requiring surgery in 5% of cases. The length of hospital stay was a median of 5 [4] days, and survival to discharge after TAVR was 100%.

| Pre-TAVR evaluation | | | | | |
|---|---|---|---|---|---|
| **Baseline characteristics (n,%)** | Age (years) (mean+ SD) | 80.8 ± 7.4 | **Preprocedural scores (n,%)** | | |
| | Male (n, %) | 25 (62.5%) | KATZ activities of daily livings (ADL) questionnaire | | |
| | Arterial hypertension | 30 (75%) | | | |
| | Diabetes mellitus | 10 (25%) | -Independent (6 score) | 32 (80%) | |
| | Dyslipidemia | 22 (55%) | -Mild dependent (5 score) | 3 (7,5%) | |
| | Chronic kidney disease | 11 (27.5%) | -Moderate-severe dependent (≤4 socre) | 4 (10%) | |
| | Peripheral artery disease | 4 (10%) | GIJON Modified: at Risk | 2 (5%) | |
| **Cardiac disease characterization (n,%)** | Aortic valve disease (predominant lesion) (n,%) | | FRAIL | | |
| | Aortic stenosis | 37 (92.5%) | -No frail | 10 (25%) | |
| | Aortic regurgitation | 3 (7.5%) | -Prefrail | 19 (47.5%) | |
| | | | -Frail | 10 (25%) | |
| | LVEF (%) (mean+SD) | | MMSE (mean+SD) | 26, 2 ± 6 | |
| | Normal | 60.8 ± 9.5 | ≤ 26 (n,%) | 7 (17.5%) | |
| | Mild depresed | 29 (72.5%) | ≤24 (n,%) | 4 (10%) | |
| | Severe depresed | 10 (25%) | SF36 (median and IQR) | 47.2 [27] | |
| | RV dysfunction (n,%) | 1 (2.5%) | EXPECTATIONS PRE-TAVR | | |
| | NYHA Class (n,%) | 5 (12.5%) | -Bean able to walk up and down stairs | 13 (32.5%) | |
| | I | 6 (15%) | -No or less fatigue | 38 (95%) | |
| | II | 20 (50%) | -No dizinnes | 3 (7.5%) | |
| | III | 9 (22.5%) | -No palpitations | 3 (7.5%) | |
| | IV | 4 (10%) | SATISFACTION PRE-TAVR NURSE CLINIC | 9.8 ± 0.9 | |
| **Blood test (mean + SD or median and IQR)** | Creatinine (mg/dl) | 1.04 ± 0.4 | -Receive proper and comprehensive information about my intervention | 9.83 ± 0.8 | |
| | Hemoglobine (g/dl) | 12.3 ± 2.4 | -Being able to actively participate in my own care | 9.85 ± 0.6 | |
| | NT-proBNP (pg/mL) | 1998 [2747] | -Receive proper and comprehensive information about my follow up and care at home | | |
| **TARV admission** | | | | | |

| | | | Complications (n,%) | |
|---|---|---|---|---|
| **TAVR outcome (n,%)** | Successful implant | 18 (45%) | Vascular | |
| | Mild aortic regurgitation | 18 (45%) | -Minor (Haematoma) | 10 (25%) |
| | Moderate-severe aortic regurgitation | 2 (5%) | -Mayor (ischemia, AV fistula, pseudoaneurysm) | 5 (12,5%) |
| | Simultaneous revascularisation | 6 (15%) | -Requiring surgery | 2 (5%) |
| | | | -Requiring percutaneos anglioplasty | 3 (7.5%) |
| **Survival (n,%)** | Survival at discharge | 40 (100%) | Pacemaker implant | 15 (37.5%) |
| | | | Stroke (Ischemic/ Hemorrhagic) | 2 (5%) |
| | | | Renal replacement therapy | 2 (5%) |
| | | | Cardiac tamponade | 3 (7.5%) |
| | | | Transfusion | 6 (15%) |

## Discussion

This manuscript describes an innovative protocol for nursing preparation of patients undergoing TAVR as well as the initial experience in the first months of post-implantation follow-up, providing evidence to guide the way in which nurse-led care is provided to the TAVR patient.

There is extensive evidence on the role of nursing in patient education, e.g., in heart failure (HF), transplantation and cardiac surgery [23]. Nursing interventions in this area help the patient/family to be more informed and better prepared for surgery or transplantation. In addition, nursing is particularly important as a point of patient/family contact during the process and in the preparation of the patient for discharge [24].

Both the patient and the family express concern about their health condition, their survival and/or the success of the procedure or treatment [25], so the availability of social support and coping strategies, as well as knowing what steps should be taken, are essential for discharge and for an adequate recovery [26]. Ettema [27], in his PREDOCS program, describes how a nursing intervention in the 2-3 weeks prior to cardiac surgery helps to detect at-risk or frail patients and promotes adequate preparation, which helps to reduce complications. The use of brochures or videos, and allowing time for the patient to ask questions, can help during the process. In general, it is observed that educational nursing programs (pre- and post-interventional procedures, HF, cardiac rehabilitation,) have been shown to reduce readmissions, length of hospital stay, anxiety, and contribute to improving the quality of life and functional capacity of patients and help to reduce healthcare costs [28-32].

TAVR program include heart teams, where the nurse has a pivotal role during the whole process from diagnosis to intervention and then in the follow-up after implantation. However, currently nurse participation and leadership in TAVR programs are anecdotal. Nursing expertise in cardiovascular care is vital in preparing the patient for the TAVR process and in providing appropriate health education for both the procedure and discharge, understanding the patient's own and clinical needs, being able to adapt care pathways, plan the procedure and monitor recovery, maintaining contact with the patient during admission and at the patient's own home [4]. This nursing leadership capacity led to the development of the TAVR nurse role, which emerged to improve the quality of care and clinical outcomes in patients undergoing TAVR. Hawckey et al [15] and Lauck et al [23] described the competencies and responsibilities of the TAVR nurse role, which has been a fundamental step towards the creation of the emerging TAVR nurse protocols.

There is experience in different countries that have already implemented their TAVR nurse protocol with excellent results. Nurse leadership and teamwork skills have helped TAVR nurse to become an essential pillar in standardizing care for these patients[13-16,23,34-36]. Spain has recently drawn up a national framework protocol, which must be adapted to the local characteristics of each center [37].

Our protocol is based on the competencies and responsibilities described for the TAVR nurse, creating a TAVR nurse team in the hospital selecting nurses specialized in cardiovascular care.

We focused in nurse provided patient/caregiver health education, expanding knowledge about their disease, TAVR

preparation and the whole procedure. The use of specific education and preparation material (slides and brochure) included in our protocol in the pre-TAVR consultation resulted in high patient satisfaction. The mean response regarding satisfaction after the pre-TAVR consultation was 9.8 out of 10, reflecting the importance the patient gives to being informed, knowing what steps are being followed and to be considered at the center of the process. Canale A [16] has already described how nurse-led educational program enhances the preparation and motivation of the TAVR nurse herself for the project, making a commitment to the program and to the patient. It is important to spend time and resources educating and informing patients as it empowers them to become an "informed patient", better prepared and empowered in his healthcare. It is key to establish a trusting relationship so patients can express their concerns, which will help the individuals to reduce anxiety about the procedure and to feel that they are a fundamental part of the process.

On the other hand, a global assessment of the patient, including functional status, is essential both in the indication of TAVR and in the final result of the intervention [17,38]. Despite all this, a global functional status pre-TAVR is not always performed because it can be time-consuming, difficult to define precisely and fairly subjective, so different risk factors are often not addressed or included when planning the care. Therefore, our project included a selection of the scales and questionnaires to evaluate the frailty, dependence, social situation, quality of life and cognitive function.

Frailty is a clinical syndrome that occurs during ageing, is characterized by a decrease in physiological reserve under stress and constitutes a state of vulnerability that carries a higher risk of adverse outcome. Its prevalence in Spain is high, especially in elderly people with comorbidity and chronic diseases [39]. In the case of cardiovascular disease, frailty determines worse clinical outcomes, with higher morbidity and mortality in all scenarios, acute and chronic; including worse outcomes after TAVR [40-41]. Frailty has been associated with an increased risk of in-hospital mortality, readmission, incidental disability, or functional impairment, and carries a higher incidence of complications and mortality at one-year post-procedure, which is likely to have more impact on the level of independence than the AS per se. Therefore, frailty assessment can guide important clinical decisions through a better understanding of patient vulnerability and risk [42-46] and should be taken into account for individualized treatment and care plans [39].The Katz Index is a widely validated scale and <6 score was identified as a significant independent predictor of long-term all-cause mortality after TAVR [41]. We found a significant percentage of our population in a situation of fragility and dependency, and even more so in a pre-frail condition.

Regarding the cognitive function evaluation, we found 10% of patients with cognitive impairment. This situation is a risk factor for postintervention delirium, increased mid-term mortality, increased length of stay and progressive [47].

The identification of frail, dependent, with cognitive impairment, or in a situation of social risk patients, through scales applied by nursing could help to select the best candidates for TAVR and individually plan the procedure. These scales can be arranged by nursing and the availability of the TAVR nurse represents an opportunity to achieve the global assessment of TAVR patients, being crucial in higher-risk patients [23].

Finally, in spite of the extensive evidence on TAVR and clinical outcomes, few studies examine preprocedural patient expectations [14,48-49]. Others focus at expectations at one year post implantation when assessing patient experience during the programme [50]. This fact motivated the inclusion in our study an ad hoc assessment of patient expectations during the pre-TAVR consultation (informed about risks, limitations and benefits), which reflected the greatest concerns and desires of the patient regarding his disease and intervention.

The limitations of the study are related to the fact that it is a retrospective single-center study, which could reduce the extrapolation of the conclusions. Larger scale multicenter studies are needed to establish this protocol as a standard for future implementations in other centers. A further limitation is that there was not a control group. After the implementation of our TAVR nurse protocol over time, we hope to analyze its influence on the results of the procedure in the short and medium term. We believe that there will be challenges to be faced responding to program growth such as bottlenecking of patients waiting for evaluation and the timely and efficient work up with patients along the pathway.

## Conclusions

Implementing TAVR programs which include a consensus-driven protocol developed by nursing for pre- and post-procedural, with a patient-centered approach, is feasible. TAVR nurse-led care including pre-TAVR evaluation could help to improve the patient education, resolve questions, better pre-procedure preparation, prevent complications and increase patient satisfaction throughout the TAVR process.

Frailty, dependence and cognitive impairment are associated with poorer outcomes and are common in AS patients undergoing TAVR, and its pre-procedure evaluation can be carried out effectively by nursing. This could help to select and prepare the patients appropriately and thus achieve better outcomes.

Further studies and validation of TAVR nurse protocols in larger populations are needed.

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