

Impact of a PROgram of Cardiovascular nurse interventionS in a VALVular haEmodynamic Unit (PROCESS-VALVE) on Quality Indicators: A Quasi-Experimental Ambispective Study

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Background: The percutaneous treatment of heart valve diseases carried out in the hemodynamic service is constantly growing. After analyzing the mortality, readmissions, success of the procedure, and complications, several studies support this type of percutaneous procedure. The increase in these procedures has required the creation of multidisciplinary teams and new diagnostic and care circuits, such as presurgical consultations and postsurgical follow-ups. Even so, there is little evidence regarding the effect of these consultations on quality indicators.

Purpose: The objective of this study is to evaluate the impact of a program of presurgical and postsurgical nurse interventions (PROCESS-VALVE) on quality indicators of the health of patients undergoing percutaneous valve procedures.

Patients and Methods: The influence of presurgical and postsurgical consultations on quality indicators will be evaluated through an ambispective quasi-experimental study. Patients will be recruited at a tertiary-level hospital in Barcelona, Spain. For the control group, data will be collected retrospectively from patients who underwent percutaneous valve procedures but did not receive pre- or postsurgical consultations. The intervention group comprises those patients agreeing to participate in the study and the hemodynamic nurse valve consultation program (PROCESS-VALVE). In addition, we will assess whether a face-to-face postsurgical consultation equally improves quality indicators compared to postsurgical telephone consultation; for this, a sub-study will be carried out comparing face-to-face or telephone postsurgical follow-up by means of a randomized controlled clinical trial with simple blinding in the intervention group.

Discussion: This study will generate scientific evidence regarding the impact on quality indicators of a nursing intervention via presurgical and postsurgical consultations. In addition, it will allow us to decide the most appropriate follow-up strategy for this type of patient.

Trial Registration: ClinicalTrials.gov NCT05179278, registration date 01/05/2022.

Keywords: valvular heart disease, nurse consultation, health indicators, postsurgical follow-up

Introduction

Heart valve diseases form part of a group of heart disorders that are highly prevalent and often require long-term diagnostic and therapeutic procedures.¹ Currently, aortic stenosis (AS) is the most prevalent heart valve disease in Europe, followed by mitral regurgitation (MR).² In both heart valve diseases, a degenerative cause is the most frequent etiology.³ In addition, it should be noted that tricuspid regurgitation (TR) has a high prevalence in patients diagnosed with MR, with an estimated annual incidence in Europe and the United States of 200,000–300,000 patients.⁴

For these patients, the clinical practice guidelines⁵ define corrective cardiac surgery as the treatment of choice, although the treatment choice depends on multiple factors.⁵ In fact, different studies reported that 47% of patients diagnosed with MR⁶ and 49% of those with AS⁷ were denied surgery. In these cases, clinical practice guidelines establish that these patients may benefit from percutaneous treatments if they meet the established requirements, even patients with intermediate surgical risk could also benefit from these procedures.⁵

Moreover, recent studies confirm the effectiveness of percutaneous valve treatments. Patients with medium and low surgical risk undergoing transcatheter aortic valve implantation (TAVI) compared with surgical valve replacement surgery have better mortality data, lower complication rates, and fewer admissions.⁸ The literature concluded that this treatment and other percutaneous MR and TR procedures have high success rates,^{9–11} low rates of complications, adverse effects,^{9,10} and mortality,^{9–11} and improve patient's functional capacity¹¹ and quality of life.^{12,13} Therefore, percutaneous techniques offer a less invasive and more effective alternative for the treatment of heart valve diseases.

Irrespective of the treatment modality, hemodynamic services have experienced a significant increase in activity, requiring the creation of new action circuits, at the diagnostic level but also for patient care throughout the surgical process. In this sense, different studies have highlighted the need to form multidisciplinary teams to agree on the most appropriate treatment for these patients and to effectively manage the process from diagnosis to treatment.^{5,14}

On the other hand, Hawkley¹⁵ emphasized that patients require standardized education regarding the preparation, expectations, and length of hospital stay in order to plan the admission process, procedure, and discharge; this educational orientation can reduce presurgical anxiety and length of hospital stay. Along these lines, other studies also confirm the positive effect of a nurse educational intervention on anxiety on both patients undergoing surgery¹⁶ and cardiac catheterization.¹⁷

A nurse intervention via a personalized interview involves the creation of a care process before the scheduled intervention and provides information, knowledge of self-care, counselling, and reduction of anxiety and fear.¹⁸ The information provided should deal with the procedures to be performed on the patient and include relevant information about the preoperative, intervention, and postoperative periods, and has been described to directly influence patient satisfaction.¹⁹ In fact, Bagés-Fortacín²⁰ concluded that a structured presurgical visit has positive results on the level of anxiety, self-control of fear, treatment knowledge, comfort and pain levels. For all these reasons, here we create a program of personalized nurse interventions for patients undergoing TAVI procedures called PROgram of Cardiovascular nurse interventionS in a VALVular haEmodynamic unit (PROCESS-VALVE).

Health quality indicators are measurable elements used to assess and evaluate the quality of healthcare services provided to individuals or populations. These indicators help gauge various aspects of healthcare delivery, outcomes, and patient experiences to determine the effectiveness, safety, and efficiency of healthcare systems; they can encompass a wide range of measures being classified as structural, process, or outcome indicators. At the international level, the Canadian Cardiovascular Society (CSS), through the CCS TAVI Quality Working Group, proposed seven items to evaluate percutaneous aortic valve implantation via quality indicators.²¹ They proposed evaluation by a multidisciplinary committee (Heart-Team) with waiting time as a structural indicator, and the evaluation of surgical risk and quality of life before and after the intervention, mortality, and rate of readmissions per year as process indicators. In 2019, this group also added other indicators such as the need for pacemakers and the length of hospital stay.

At the national level, for this type of percutaneous treatment, the Ministry of Health and the Galician Technology Assessment Agency developed 23 health quality indicators.²² Among others, process indicators such as the implementation of the evaluation of the patient's autonomy level, frail elderly syndrome assessment, and patient evaluation by a multidisciplinary team, stood out; the success of the procedure, mortality, improvement of functional capacity, readmissions, hospital stay, and adverse effects associated with implantation were outcome indicators. Also at the national level, in the case of percutaneous MR treatment, the Spanish Society of Cardiology proposed indicators such as the success of the procedure, complication rate, and mortality, among others.²³

For the evaluation of a pre- and/or postsurgical nurse follow-up consultation, there are currently no indicators described in the literature. However, the "National Database of Nursing Quality Indicators"²⁴ proposes different indicators that can be extrapolated to this consultation, such as patient satisfaction and the outcome indicator of nosocomial infections. Regarding nurse follow-up after a percutaneous procedure for valvular pathology, there is scant

evidence. On the other hand, a postsurgical nurse follow-up intervention has been described to reduce readmissions and improve the satisfaction of patients undergoing cardiac surgery.²⁵

Despite all the above, there is no available evidence evaluating the direct impact of presurgical and postsurgical consultations on patients undergoing a percutaneous valve procedure in the hemodynamic service.

This study aims to evaluate the impact on quality indicators of the PROCESS-VALVE program. This is the first quasi-experimental study to analyze the impact of a program of hemodynamic nurse valve consultations (PROCESS-VALVE), consisting of a pre and postsurgical consultation, on the following quality indicators: waiting time, patient satisfaction, length of hospital stay, hospital readmission, mortality, in-hospital complications, and nosocomial infections in patients undergoing percutaneous valve procedures.

Main Objective

The overall aim is to evaluate the impact of the nursing hemodynamic program PROCESS-VALVE, consisting of a presurgical preparatory consultation and a postsurgical follow-up consultation, on the quality indicators of patients undergoing percutaneous valve procedures. Six quality indicators will be evaluated: waiting time, hospital stay, patient satisfaction, hospital readmission, mortality rate, surgical complications and nosocomial infections.

We hypothesize that the nursing hemodynamic PROCESS-VALVE program will improve all the quality indicators mentioned above when compared with those patients not following the program.

The secondary objectives are:

- To evaluate the impact of the PROCESS-VALVE nursing program on the quality indicators described, as well as on clinical and sociodemographic factors.
- To describe the impact of the presurgical consultation on pre-intervention anxiety in patients undergoing percutaneous valve procedures.
- To compare clinical and sociodemographic factors and the influence on the quality indicators described in patients undergoing percutaneous valve treatment, comparing those who had a post-intervention nurse face-to-face vs telephone follow-up.

Materials and Methods

Study Design and Settings

This study has been designed as an ambispective quasi-experimental study. At the moment, our standard of care for all patients undergoing TAVI procedures in our hemodynamic unit is the PROCESS-VALVE program consisting of a pre and postsurgical consultation follow-up of all patients. Therefore, the control group will be those patients who underwent surgery before October 2019, prior to the creation of the PROCESS-VALVE nurse consultation program; for this group, data will be collected retrospectively and consecutively. The intervention group will be those patients that fulfil the inclusion criteria and agree to participate in the PROCESS-VALVE nursing program. This program was implemented in our unit in October 2020. The intervention group will be recruited during the presurgical hemodynamic nurse visit and will finally be operated on in our center.

Patient recruitment will be carried out in the Hemodynamic Unit of the Hospital de la Santa Creu i Sant Pau (Barcelona, Spain). This is a tertiary-level hospital with extensive experience in the percutaneous treatment of cardiac valve pathology and a national reference. The center's area of influence for this type of procedure is formed by the Area Integral de Salut Barcelona Dreta and Litoral Mar (Comprehensive Health Area Barcelona Right and Littoral Mar) of the city of Barcelona with an accumulated population of 710,000 patients. In addition, patients from different parts of the Catalan territory are referred to our center.

To study whether the quality indicators improve according to the type of postoperative follow-up (face-to-face or telephone), a randomized controlled clinical trial with simple blinding has been designed using simple randomized sampling that will assign the sample to the face-to-face or telephone follow-up group (ClinicalTrials.gov NCT05179278, registration date 01/05/2022 and last update 22/05/23). The face-to-face follow-up group will receive the presurgical

nurse consultation with subsequent nurse follow-up in the format of face-to-face consultation one month after the intervention; the telephone follow-up group will attend the presurgical consultation and then follow up with the nurse via a telephone consultation one month after the intervention. Both groups will receive a postsurgical telephone follow-up consultation one year after the intervention. For the random assignment of patients in the trial, an ad hoc syntax will be used for this project, using the IBM-SPSS statistical package language (V26.0), in such a way that it is perfectly balanced and with an established block size (Figure 1).

Inclusion and Exclusion Criteria

The target population are those patients diagnosed with valvular disease undergoing percutaneous treatment at our center.

Patient inclusion criteria: age ≥ 18 years, accepted for percutaneous intervention of stenosis/aortic insufficiency, mitral regurgitation, and tricuspid regurgitation; non-illiterate, and with no language barrier.

Patient exclusion criteria: patients operated on urgently for stenosis/aortic insufficiency, mitral regurgitation, and tricuspid regurgitation, and long-term hospitalized patients who require intervention in the same admission.

Sample Size

For sample calculation for the clinical trial, the variance of both groups was used for the subjective expression of overall satisfaction. 90 subjects will be required in the first group and 90 in the second group to detect a statistically significant difference between two proportions. It is expected that the proportion for Group 1 will be 0.6 and 0.8 for Group 2.

Additionally, for the validation of this calculation, the Type I error must be set at the usual value of 5% ($\alpha=0.05$), with a bilateral approximation and a minimum power of 80% (beta error = 0.20). The possibility of losses was also estimated at 10% (GranMo 7.12 with an approximation of the ARSINUS).

Therefore, for the main design, 180 patients will be retrospectively and 180 prospectively collected. For the random assignment of patients to the trial, a syntax expressed for this project will be used, using the IBM-SPSS statistical package language (V26.0), in such a way that it is perfectly balanced and with a set block size.

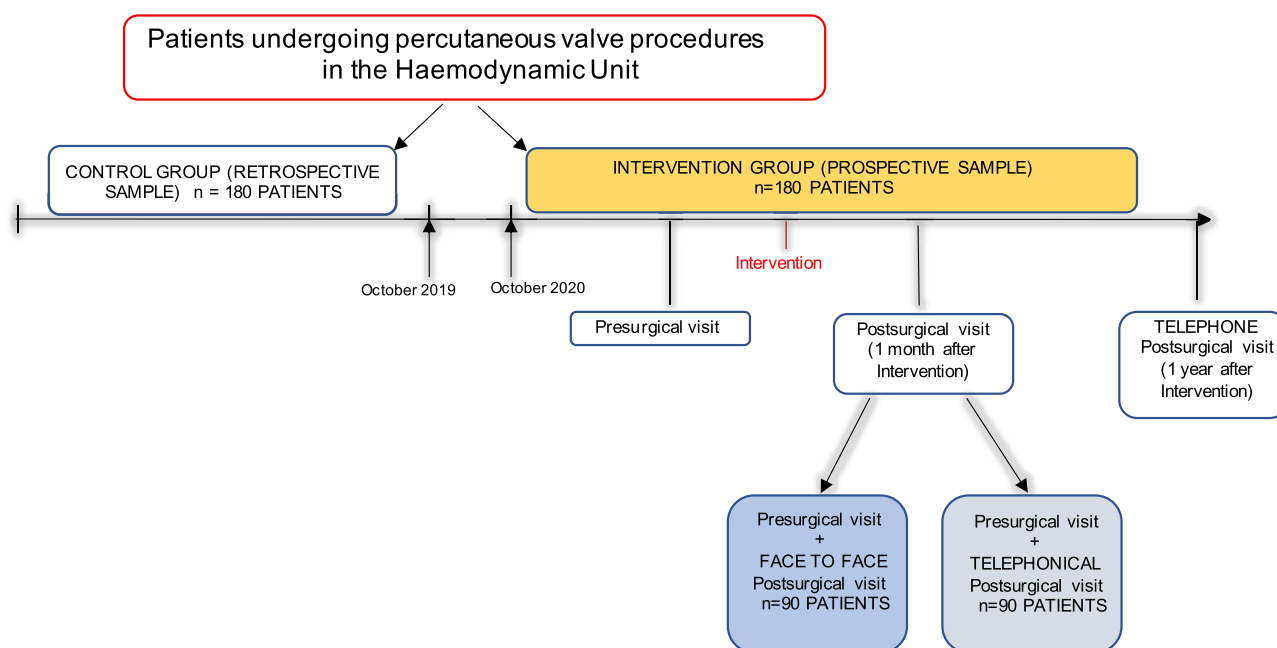


Figure 1 Schematic view of the study design.

Randomization and Blinding

For the ambispective quasi-experimental design, consecutive sampling will be carried out with retrospective and prospective data collection.

In the clinical trial analyzing the type of postsurgical follow-up (face-to-face or telephone), a simple randomization will be performed. For the random assignment of clinical trial patients, a syntax created for this project using the IBM-SPSS statistical package language (V26.0) will be used in such a way that it is perfectly balanced and with a set block size.

Intervention Design

Process-Valve

The PROgram of Cardiovascular nurse interventionS in a VALVular haEmodynamic unit (PROCESS-VALVE) consists of a presurgical visit and a postsurgical follow-up visit.

Presurgical Visit

Participants from the intervention group of the main study will have a presurgical consultation where they will receive written and verbal information about the valvular pathology, the surgical intervention to be performed, possible complications and risks of this intervention, and a schedule will be proposed with recommendations after the intervention (waiting list, length of hospital stay, and home mobilization guidelines).

In addition, during this visit, the patient will undergo a comprehensive assessment to verify previous diagnostic tests, assess the patient's autonomy, frailty, and quality of life before the intervention, and analyze family support after the intervention. With this, any possible needs of the patient and family are detected throughout the process and adequate and effective care coverage is managed at all times.

During the presurgical visit, the patient and family will also receive psychological preparation and information regarding care before, during, and after the intervention, ensuring the safety of the patient at all times during their surgical process.

The nurse visit takes place in the Hemodynamic unit itself, in a private environment made available to the patient and a family member. This intervention is performed by expert nurses in valvular pathology and its prior, intraoperative, and postoperative treatment. A visit time of 30 minutes is established. Information leaflets have been designed to reinforce knowledge and focus on key points.

Postsurgical Visit

In the follow-up after percutaneous surgery of the valvular pathology, the patient will be randomized to the FACE-TO-FACE or TELEPHONE GROUP. Both groups will conduct two follow-up nursing visits after the 15–20-minute intervention (Table 1).

This postsurgical consultation aims to reinforce the information provided in the presurgical visit, reassess needs, confirm the steps previously taken, comprehensively re-evaluate the patient and compare with their previous state, ensure patient safety, provide emotional support, monitor possible complications during the hospital stay, detect late surgical complications, and manage the diagnosis and treatment circuit.

Outcome Assessment. Variables and Measurement Instruments

The independent variables of the study are the aforementioned presurgical and postsurgical nursing consultations.

To evaluate the impact of these nurse interventions (PROCESS-VALVE) on quality indicators,^{22–24} the following dependent variables were established:

Table 1 Chronology of the Post-Surgical Visits

Face-to-Face Group	Telephone Group
Visit 1: face-to-face 4 weeks after PS	Visit 1: by phone 4 weeks after PS
Visit 2: by telephone 1 year after PS	Visit 2: by telephone 1 year after PS

Abbreviation: PS, percutaneous surgery.

- *Waiting time*: this indicator is established as the time between acceptance for percutaneous treatment by the multidisciplinary team and the intervention day.
- *Hospital stay*: this indicator is defined as the time elapsed from the intervention to hospital discharge. An overall value for the number of days in hospital will be used, as well as a differentiation between the days in intensive care and the hospitalization unit.
- *Patient satisfaction*: for the subjective perception of patient satisfaction, an adaptation of the validated questionnaire SUCMA 14²⁶ will be used. This instrument measures user satisfaction for major outpatient surgery, consists of 14 questions with four possible Likert-type answers, and does not establish an overall score. The adaptation of the questionnaire has been carried out with the permission and acceptance of its author and two questions have been modified to adapt it to the objective of the study. In addition, a question has been added to evaluate the satisfaction of the entire process with six possible Likert-type answers.
- *Hospital readmission*: defined as any hospital admission after discharge. A distinction will be made between cardiological/non-cardiological causes and we will analyze if this is due to a postsurgical complication. It will be evaluated one month after discharge and one year after the intervention.
- *Mortality*: cardiac and non-cardiac mortality will be differentiated and analyzed during the intervention and hospital stay, after 30 days, and one year after the intervention.
- *Surgical complications*: the following will be evaluated during the intervention and hospital stay, after 30 days, and one year after the intervention:
 - Stroke.
 - Severe conduction disorder requiring definitive pacemaker implantation.
 - Heart complications requiring surgical intervention.
 - Serious vascular complications requiring surgery or blood transfusion to correct severe bleeding.
- *Nosocomial infections*: urinary, respiratory, surgical site, and catheter-associated bacteremia acquired during the hospital stay.

The confounding variables of this study are sociodemographic and clinical data (sex, age, pathological history), pre-intervention anxiety (STAI E-R questionnaire), surgical history, and knowledge prior to the information received.

Statistical Analysis

Data analysis will be carried out using the SPSS statistical software package. Initially, all results will be described. For this, the quantitative variables will be presented as mean and standard deviation or median and interquartile range. Categorical variables will be reported as frequency and percentage.

McNemar's Test will be applied to analyze categorical variables, the Wilcoxon Test for ordinal variables, and the repeated-measures *t*-test for quantitative variables.

The probability of making a type-I error is set at 5% ($\alpha=0.05$) with a bilateral approximation.

Discussion

The overall objective of this research project is to improve the quality indicators of patients undergoing a percutaneous valve procedure by implementing the PROCESS-VALVE program.

The literature has demonstrated that a presurgical nursing consultation can reduce perioperative anxiety,^{17,20,26,27} which leads to reduced perioperative pain and risk of infection,²⁸ a decrease in rhythm disorders and myocardial ischemia,^{17,29,30} shorter hospital stays,^{20,31} and increased patient satisfaction.³² Nevertheless, there is no evidence regarding the influence of a surgery preparation consultation on percutaneous valve procedures in terms of quality indicators.

There is no scientific evidence regarding the influence of a postsurgical nurse follow-up on this type of patient. Nonetheless, nurse follow-up has been described to reduce readmissions and increase patient satisfaction in cardiac^{24,32} and orthopedic surgery.²⁵ On the other hand, the COVID-19 pandemic caused an increase in telephone medical consultations and telemedicine for the follow-up of surgical patients. Along these lines, studies

demonstrated non-inferiority for telephone follow-up in terms of patient satisfaction, readmission, and cardiac complications.^{33–37} This project also aims to compare the quality indicators of face-to-face and telephone post-surgical follow-up.

In the initial phases of this project, we proposed an experimental study to evaluate the main objective. For the creation of the nursing program of this study, multidisciplinary meetings were held that afforded a global approach to intervention and innovation in the treatment of patients operated for valvular pathology. Therefore, we evaluated the benefit of conducting a clinical trial between the new program and current usual practice (no prior consultation and only clinician follow-up). The authors of the study and the center's management considered that this program would certainly have an impact on patients, thus the experimental study was dismissed. This is why retrospective data collection before implementation of the program was carried out to compare both realities. Being aware of the limitations and lower impact of this design, we chose it in order to benefit as many patients as possible.

We also believe that this study can contribute to knowledge on how to implement a more patient-centered healthcare in a clinical context, placing greater prominence on the patient and how they perceive the medical attention.³⁸ Moreover, it would also be feasible to implement this protocol in other centers.

In conclusion, this study will generate evidence regarding the influence of a nurse intervention in patients undergoing percutaneous valve procedures via a presurgical consultation and subsequent nursing follow-up. In addition, it will add new evidence regarding the dichotomy of the two types of follow-ups (face-to-face and telephone) and create evidence in the case of a postsurgical nurse follow-up in this type of patient.

Limitations of the Study

One of the limitations of this study is that it is a single-center study, which limits the generalizability of the results. To address this, we should extend it to other centers. Also, subjective tools will be used, such as anxiety and satisfaction scales. Finally, in the retrospective data collection, there may be information bias and loss of study information.

Ethics Approval and Consent to Participate

The study was approved by the IBSant Pau Research Institute (registration number: IIBSP-CEH-2020-14, Protocol Version 2, Issue Date: 15 Feb 2023) and was registered in ClinicalTrials.gov, NCT05179278, on 01/05/2022 (last update 22/05/2023). The study will be carried out according to the Declaration of Helsinki. All participants will provide informed consent before the start of the pre-surgical consultation.

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Author Contributions

All authors made a significant contribution to the work reported, whether that is in the conception, study design, execution, acquisition of data, analysis and interpretation, or in all these areas; took part in drafting, revising or critically reviewing the article; gave final approval of the version to be published; have agreed on the journal to which the article has been submitted; and agree to be accountable for all aspects of the work.

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Disclosure

The authors declare that they have no competing interests.

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