

ORIGINAL RESEARCH

# Clinical Impact of Heart Team Decisions for Patients With Complex Valvular Heart Disease: A Large, Single-Center Experience

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**BACKGROUND:** A multidisciplinary approach might be pivotal for the management of patients with valvular heart disease (VHD), but clinical outcome data are lacking.

**METHODS AND RESULTS:** At our institution, since 2014, internal guidelines recommended heart team consultations for patients with VHD. The clinical/echocardiographic characteristics, treatment recommendations, performed treatment, and early clinical outcomes of consecutive, hospitalized patients with VHD undergoing heart team evaluation were collected. Surgical risk was prospectively assessed by the EuroSCORE II and STS-PROM. The primary end point of the study was early mortality. A total of 1004 patients with VHD with high clinical complexity (mean age, 75 years; mean EuroSCORE II, 9.4%; mean STS-PROM, 5.6%; 48% ischemic heart disease; 29% chronic kidney disease, 9% oncologic/hematologic diseases) were enrolled. The heart team recommended an interventional treatment for 807 (80%) patients and conservative management for 197 (20%) patients. Management crossovers occurred in only 5% of patients. The recommended intervention was cardiac surgery for 230 (23%) patients, percutaneous treatment in 516 (51%) patients, and hybrid treatment in 61 (6%) patients. Early mortality occurred in 24 patients (2.4%) and was independently predicted by aortic stenosis, left ventricular ejection fraction, pulmonary artery systolic pressure, and conservative management recommendation. In patients referred to treatment, observed early mortality (1.7%) was significantly lower ( $P < 0.001$ ) than expected on the bases of both the STS-PROM (5.2%) and EuroSCORE II (9.7%).

**CONCLUSIONS:** Within the limitations of its single-center and observational design, the present study suggests that heart team-based management of patients with complex VHD is feasible and allows referral to a wide spectrum of interventions with promising early clinical results.

**Key Words:** cardiac surgery ■ heart team ■ hybrid interventions ■ mortality ■ precision medicine ■ TAVI ■ valvular heart disease

Valvular heart diseases (VHDs) are highly prevalent in industrialized countries.<sup>1</sup> For decades, the only possible treatment for VHD was open cardiac surgery, but surgical outcomes are known to depend

on patient conditions. Indeed, comorbidities such as ischemic heart disease (IHD), peripheral vascular disease, and chronic kidney disease often coexist with VHD<sup>2</sup> and adversely affect valve surgery outcomes.

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Supplemental Material for this article is available at <https://www.ahajournals.org/doi/suppl/10.1161/JAHA.121.024404>.

For Sources of Funding and Disclosures, see page 10.

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## CLINICAL PERSPECTIVE

### What Is New?

- In this large (>1000 hospitalized patients), single-center study, a heart team–centered decision-making process to guide the management of complex valvular heart disease was feasible (5% crossover management between interventional and conservative management).
- The heart team–based management resulted in an overall low early mortality rate (2.4%); in particular, interventional treatment was recommended for 80% of patients with complex valvular heart disease, comprised a broad spectrum of surgical, percutaneous, or hybrid operations and was associated with a lower than predicted observed early mortality.

### What Are the Clinical Implications?

- Heart team decision making is recommended by international guidelines but scientific evidence regarding its feasibility and impact in the management of patients with complex valvular heart disease are lacking.
- The present study supports the concept that heart team consultations represent a valuable clinical–decision model for patients with complex valvular heart disease.

## Nonstandard Abbreviations and Acronyms

<b>EuroSCORE</b>	European System for Cardiac Operative Risk Evaluation
<b>HT</b>	heart team
<b>IHD</b>	ischemic heart disease
<b>STS-PROM</b>	Society of Thoracic Surgeons Predicted Risk of Mortality
<b>TAVI</b>	transcatheter aortic valve replacement
<b>VHD</b>	valvular heart disease

Consequently, surgery is often denied to patients with complex VHD,<sup>2,3</sup> and surgical risk stratification becomes essential for surgery referral.<sup>4,5</sup> On parallel, novel therapeutic opportunities, including surgical techniques evolution and transcatheter technologies, became available, offering new options to treat patients with VHD. Thus, the clinical decision-making process for each patient with VHD is not easy and should take into consideration critical features (life expectancy, patient anatomy, interventional options, and local resources) usually not captured by surgical risk scores.

Starting from the concept that a multidisciplinary approach where VHD experts with different competencies may contribute to patient-centered decisions, the heart team (HT) recently obtained a central role in most of the European recommendations for VHD management.<sup>4</sup> Similarly, the last American guidelines for VHD management clearly state that patients with severe VHD should be evaluated by a multidisciplinary heart valve team when intervention is considered.<sup>5</sup> Despite such strong recognitions, randomized clinical trials and large-scale studies assessing the impact of HT on the management of patients with VHD are lacking.

We herein report the outcome data of consecutive patients with VHD who underwent HT discussion in a single tertiary center where an HT-based decision was formally set as pivotal for patient's management.

## METHODS

### Study Design and HT Characteristics

This is a single-center observational study reporting data that were prospectively collected within the framework of clinical pathway dedicated to patients with VHD of our institution (<https://www.policlinicogemelli.it/servizi-paziente/percorsi-assistenziali/valvulopatia/>).

Because of the sensitive nature of the data collected for this study, requests to access the data set from qualified researchers trained in human subject confidentiality protocols may be sent to the corresponding author.

Since 2014, internal guidelines have been implemented to promote multidisciplinary management of patients with VHD in our Institution. According to the pathway regulation, an HT-based decision has a pivotal role for management recommendations in patients with VHD. Accordingly, the only exclusion criterion for HT referral is a patient's unstable condition making management decision deferral unsafe according to the treating physician. All medical doctors at our Institution are entitled to refer patients for an HT decision. The HT of the Department of Cardiovascular Sciences has daily sessions 5 times per week (Monday–Friday), and a specific internal regulation was released on January 2014. The following physicians attend the HT sessions every day: clinical cardiologist, cardiac surgeon, interventional cardiologist, cardiac imaging specialist, electrophysiologist, vascular surgeon, and cardiac anaesthesiologist. According to the specific clinical features of the discussed patient, other figures (geriatricians, infectious disease specialists, radiologists, oncologist, etc.) are involved to provide the best assessment of the individual patient. During the HT sessions, clinical cases are presented to the staff by the attending physician (or supervised trainee) illustrating the patient's characteristics, clinical history,

cardiovascular risk factors, comorbidities, and surgical risk indexes. Definitions for main comorbidities are reported in Table S1.

Predicted operative mortality risk is graded according to both European System for Cardiac Operative Risk Evaluation (EuroSCORE) II<sup>6</sup> and the Society of Thoracic Surgeons Predicted Risk of Mortality<sup>7,8</sup> (STS-PROM) using the online calculators (<http://www.euroscore.org/calc.html> and <http://riskcalc.sts.org/stswebriskcalc/calculate>) and prospectively entered together with other key features (demographic, morphometric, and clinical) into a dedicated, structured electronic form (Figure S1).

Key images/data collected by echocardiography, cardiac catheterization, coronary angiography, computed tomography, and other diagnostic tests are displayed during the HT session and evaluated collegially. For each patient, a final HT recommendation regarding the suggested management is provided and prospectively recorded into the electronic form that enters the patient's official medical record. If additional examinations are recognized as critical to get a final decision, this request is recorded in the first HT meeting, and a second HT session is planned as soon as the results are available.

The final HT recommendations are categorized as follows:

1. Cardiac surgery
2. Percutaneous treatment (any transcatheter treatment with percutaneous approach)
3. Hybrid treatment (any transcatheter treatment with surgical access or combined surgical intervention and percutaneous intervention performed in a single procedure or in staged procedures)
4. Conservative management (medical treatment)

Of note, the recommended surgical, percutaneous, or hybrid interventions comprised both valve interventions and other cardiovascular interventions, such as surgical or percutaneous coronary revascularization and/or cardiac pacing.

After HT, the referring physician is responsible for communicating the shared decision to the patient. In the case an operation is scheduled, a cardiac surgeon or an interventional cardiologist takes direct contact with the patient in order to obtaining his/her agreement (and written informed consent to the specific intervention).

All clinical data and operation details were prospectively entered into a digitalized medical record database dedicated to cardiovascular patients (SI-cardio; Gesi, Rome, Italy), which included the HT electronic form, the echocardiographic findings, the intervention type, and the hospital discharge or in-hospital death date. Patients provided consent for the hospital records database. The study was approved by the Institution review board

(Department of Cardiovascular Sciences) as an internal validation of the clinical impact of the local HT.

According to the institutional clinical pathway dedicated to patients with VHD in our center, all echocardiograms for patients with VHD are performed by experienced physicians specialized in the imaging and care of this patient population. To enter the study, patients had to have at least 1 severe heart valve lesion. Among different echocardiographic measures, the following key parameters were considered for all enrolled patients: left ventricular ejection fraction, left ventricular end-diastolic volume, pulmonary artery systolic pressure, and tricuspid annular plane excursion. Multivalvular heart disease was defined as 1 severe VHD and at least 1 moderate heart valve lesion of another valve.

## Study Population

For the present study, all the HT electronic forms fulfilled between January 2014 and March 2019 were extracted from the hospital database. A total of 1515 HT electronic forms were identified. Patients affected by isolated IHD, infective endocarditis, or congenital heart disease were excluded. Thus, the final study population comprised 1004 patients with VHD who underwent HT discussion during the study period. Because no digitalized source of our department allowed to select patients with VHD requiring collegial discussion before 2014, no historical cohort was included in the study.

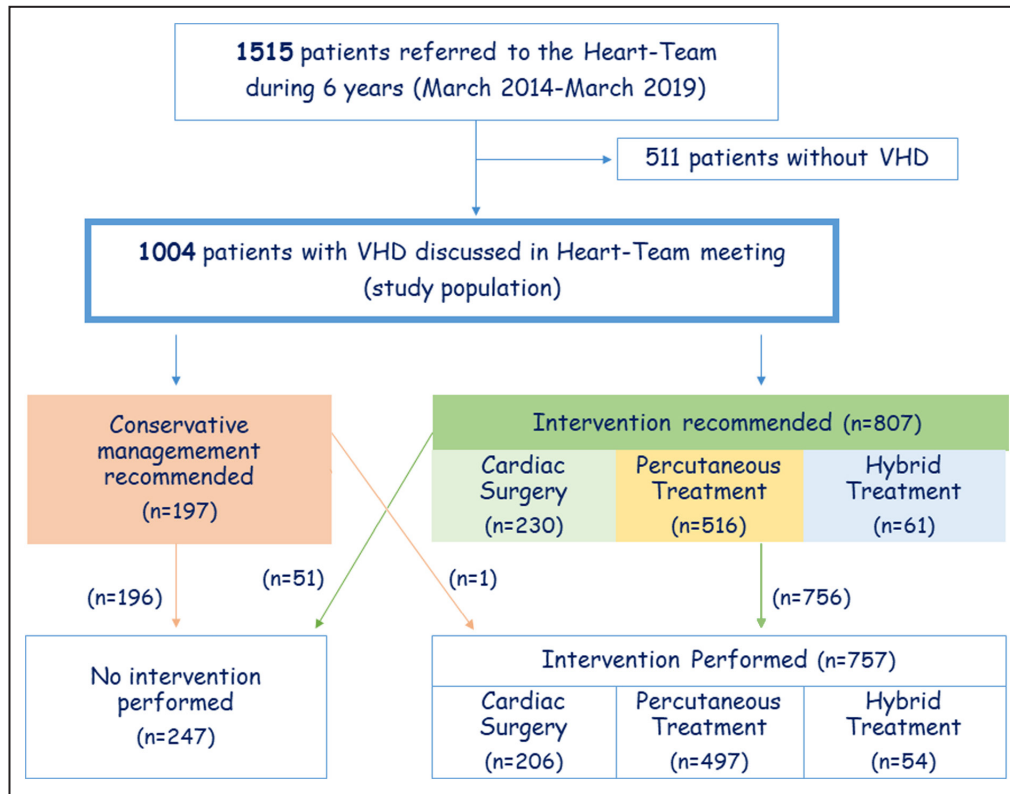
The study flowchart is summarized in [Figure 1](#). For each enrolled patient, the clinical records were revised to extract the following data:

1. Clinical characteristics (including VHD type and severity as well as main cardiovascular and non-cardiovascular comorbidities)
2. EuroSCORE II and STS-PROM
3. HT management recommendation
4. Intervention performed
5. Occurrence of death during the hospitalization when HT consultation was held
6. Occurrence of death during any further hospitalization needed to perform interventions in the case of treatment deferral

In patients in whom an intervention was recommended but was not carried out, the occurrence of death during the waiting period was also recorded.

## Study Aim and End Points

The aim of the study was to assess the outcome of a HT-based management strategy in patients with VHD. The primary end point of the present study was early all-cause mortality defined as any death occurring either during the hospitalization when the HT meeting



**Figure 1. Study flowchart.**  
VHD indicates valvular heart disease.

was held, during the waiting period for any intervention suggested by the HT, or during the hospitalization for any intervention suggested by the HT.

Subgroup analysis was planned according to “intervention recommendation” and to type of intervention recommendation (cardiac surgery, percutaneous treatment, or hybrid treatment).

To evaluate the feasibility of HT-based management, the occurrence of “management crossover,” defined as the lack of intervention in patients scheduled for any intervention or intervention performed in a patient referred for conservative management, was assessed.

### Statistical Analysis

Continuous variables were presented as mean with SD, and categorical variables as number and percentage. Comparisons of continuous variables across different groups were performed using the Student *t* test or ANOVA test (as appropriate). The  $\chi^2$  test or Fisher exact test (as appropriate) were used to compare categorical variables presented as counts and percentages.

Observed deaths were compared with expected deaths as estimated by EuroSCORE II and STS-PROM score using a  $\chi^2$  test. Because some crossovers did occur during the study, all analyses were performed by intention to treat.

A multivariable regression analysis was performed to identify the independent predictors of early death, conservative management recommendation, and management crossover among the baseline characteristics. All variables nominally significant ( $P < 0.05$ ) at a bivariate association with the selected outcome and reported in [Table 1](#) were simultaneously entered into a multivariable model to calculate their adjusted odds ratios (ORs) with associated 95% CIs. The variables included in the final regression model for conservative management recommendation and early death outcomes are listed in the corresponding tables of the Results section. A 2-tailed *P* value  $< 0.05$  was established as the level of statistical significance. All statistical analyses were performed using SPSS software version 23.0 (IBM Corporation, Armonk, NY).

## RESULTS

### Patient Baseline Characteristics

Clinical characteristics of the study population are summarized in [Table 1](#). Mean age was 75 years (50% women). Cardiovascular risk factors were common, including diabetes in 25% of the population and chronic kidney disease in 29%. As many as 40% of patients

**Table 1. Clinical Characteristics of the Study Population**

Characteristic	
No. of patients with data	1004
Age, y, mean (SD)	75 (11)
Female sex, n (%)	504 (50.2)
Body mass index, kg/m <sup>2</sup> , mean (SD)	26.4 (5.1)
Cardiovascular risk factors, n (%)	
Diabetes	250 (24.9)
Arterial hypertension	788 (78.4)
Dyslipidemia	493 (49.1)
Smoking	85 (8.5)
Comorbidities, n (%)	
Chronic kidney disease	258 (25.7)
Chronic dialysis	31 (3.1)
Peripheral artery disease	140 (13.9)
Carotid artery disease	147 (14.6)
Previous stroke	77 (7.7)
Chronic pulmonary disease	341 (34)
Neurologic disability	106 (10.6)
Systemic inflammatory and/or autoimmune disease	50 (5.0)
Oncologic or hematologic disease	94 (9.4)
Infectious disease	22 (2.2)
Ischemic heart disease	483 (48.1)
Previous myocardial infarction	149 (14.8)
Previous cardiac surgery	180 (17.9)
Clinical presentation, n (%)	
Hemodynamic instability	28 (2.8)
NYHA class III/IV	406 (40.4)
Acute coronary syndrome	61 (6.1)
Syncope	88 (8.8)
VHD cause, n (%)	
Functional	144 (14.3)
Rheumatic	112 (11.2)
Degenerative/others	748 (74.5)
VHD type, n (%)	
Aortic stenosis	694 (69.1)
Aortic regurgitation	200 (19.9)
Mitral stenosis	74 (7.4)
Mitral regurgitation	302 (30.1)
Tricuspid stenosis	2 (0.2)
Tricuspid regurgitation	196 (19.5)
Surgical prosthesis failure	36 (3.6)
Multivalvular disease	299 (29.8)
Key echo parameters, mean (SD)	
LVEF, %	52.7 (12.9)
Left ventricular end-diastolic volume, mL	112.8 (48.3)
Pulmonary artery systolic pressure, mm Hg	42.5 (15.0)
TAPSE, mm	20.5 (4.6)

(Continued)

**Table 1. Continued**

Characteristic	
Coronary angiography, n (%)	
Performed during index hospitalization	744 (74.1)
Left main stenosis	31 (4.2)
Left anterior descending stenosis	252 (33.9)
Left circumflex artery stenosis	168 (22.6)
Right coronary artery stenosis	160 (21.5)

LVEF indicates left ventricular ejection fraction; NYHA, New York Heart Association; TAPSE, tricuspid annular plane excursion; and VHD, valvular heart disease.

presented with New York Heart Association class III/IV, and half of the patients (48.1%) had concomitant IHD.

Most VHDs had organic causes (86%), and the most frequent valvular lesion was aortic stenosis (69%) followed by mitral regurgitation (30%); ~30% of the patient population had multivalvular heart disease. At echocardiography, mean left ventricular ejection fraction was 53%, and the mean pulmonary artery systolic pressure was 42 mm Hg.

Overall, the predicted surgical risk was high as estimated by a mean EuroSCORE II of 9.4% and a mean STS-PROM score of 5.6%. Of note, a sizeable subgroup of patients had important noncardiac comorbidities, including 9% with oncologic or hematologic diseases and 5% with systemic inflammatory or autoimmune diseases.

## HT Recommendations and Their Determinants

After multidisciplinary discussion, the HT assigned 807 (80%) patients to interventional treatment and 197 to conservative management (20%) (Figure 1). The recommended intervention was cardiac surgery for 230 (23%) patients, percutaneous treatment in 516 (51%) patients, and hybrid treatment in 61 (6%) patients. At multivariate analysis, previous stroke, infectious disease, hemodynamic instability, absence of aortic stenosis, and tricuspid annular plane excursion were the only independent predictors of referral to conservative management (Table 2).

The management strategy recommended by the HT was effectively carried out in the majority of patients. Indeed, management crossover was observed in 5% of cases: 1 patient referred for conservative management received intervention, and 51 referred for intervention were not operated. Among all baseline characteristics, neurological dysfunction and presentation as acute coronary syndrome were significantly associated with management crossover at univariate analysis, but this finding was not confirmed at multivariable analysis.

## Interventions Details

Overall, 757 patients received an intervention: in 411 patients, the intervention was performed during the same hospitalization as HT consultation (time to treatment, 4±8 days) and in 346 cases during a delayed scheduled hospitalization (time to treatment, 66±88 days). The interventions performed respected the HT suggestion in most of the study population except for 9 patients who received an intervention that differed from that suggested by the HT (as a result of the patient's preference for a specific treatment). Table 3 reports the details of the interventional management stratified according to HT indication. In 69 patients, the valve treatment was considered not indicated and other cardiovascular treatments were performed (coronary surgery in 10 patients, percutaneous coronary intervention in 52 patients, cardiac resynchronization therapy in 7 patients). Of note, over time, recommendations for percutaneous treatment (but not surgery) showed a significant increase (Table S2).

## Predictors of Early Mortality

Of 1004 patients with VHD referred for HT, 24 patients (2.4%) died. Most of them (15/24) died during the HT hospitalization, whereas a minority (6 patients) died during the waiting period for the scheduled intervention or (3 patients) during the hospitalization needed for a deferred intervention. During the study, mortality rates were stable (Table S2).

Patients referred by HT to conservative management had higher mortality compared with those referred to intervention (5.1% versus 1.7%;  $P=0.006$ ), but the observed mortality was significantly lower ( $P=0.046$ ) than that predicted (in the case of systematic cardiac surgery performance) by EuroSCORE II (9.2%) and numerically lower ( $P=0.21$ ) than that expected on the bases of the STS-PROM (7.4%).

At multivariable analysis, aortic stenosis (adjusted OR, 2.348 [95% CI, 0.986–5.590]), left ventricular ejection fraction (adjusted OR, 0.964 [95% CI, 0.933–0.996]), pulmonary artery systolic pressure (adjusted

OR, 1.041 [95% CI, 1.014–1.068]), and conservative management recommendation (adjusted OR, 11.077 [95% CI, 2.537–48.363]) independently predicted death in the study population (Table 4).

## Mortality According to Recommendation and Treatment

Patients referred by HT to interventions exhibited an early mortality of 1.7% (13 of 807) that was significantly lower than expected on the bases of the STS-PROM (5.2%;  $P<0.001$ ) and EuroSCORE II (9.7%;  $P<0.001$ ) (Figure 2).

When assessing the specific treatment recommendation by HT, 230 patients were referred to cardiac surgery, 516 to percutaneous treatment, and 61 to hybrid treatment. The key characteristics of patients referred to cardiac surgery, percutaneous treatment, and hybrid treatment as well as the specific interventions performed are reported in Table 3.

Patients referred to cardiac surgery received the recommended intervention in 88% of cases. The mortality observed in patients referred to cardiac surgery was 2.2% and was not different from that predicted by both the EuroSCORE II (2.9%;  $P=0.51$ ) and STS-PROM (3.0%;  $P=0.46$ ) (Figure 3). Similar results were observed in “as treated” analysis: 1.5% observed mortality in patients who received cardiac surgery versus 3.0% EuroSCORE II ( $P=0.19$ ) and versus 2.9% STS-PROM ( $P=0.21$ ).

Patients referred to percutaneous interventions received the recommended intervention in 95% of cases. The mortality observed in patients referred to percutaneous interventions was 1.7% and was significantly lower than that predicted by both the EuroSCORE II ( $P<0.001$ ) and STS-PROM ( $P<0.001$ ) (Figure 3). Similar results were observed in “as treated” analysis: 1.0% observed mortality in patients who received percutaneous treatment versus 12.9% EuroSCORE II ( $P<0.001$ ) and versus 6.1% STS-PROM ( $P<0.001$ ). Of note, in the large subgroup of 450 patients treated by transcatheter aortic valve intervention (TAVI), the predicted mortality according to the Society of Thoracic Surgeons/

**Table 2. Predictors of Conservative Management Recommendation by the Heart Team**

Characteristic	<i>P</i> univariate	<i>P</i> multivariate	Adjusted OR (95% CI)
Previous stroke	0.018	0.036	1.88 (1.042–3.407)
Infective disease	<0.001	0.029	3.112 (1.127–8.597)
Hemodynamic instability	0.001	0.033	2.711 (1.083–6.787)
Aortic stenosis	<0.001	0.010	0.554 (0.354–0.867)
Aortic regurgitation	0.004	0.186	1.349 (0.866–2.100)
Mitral regurgitation	<0.001	0.421	1.224 (0.748–2.003)
Surgical prosthesis failure	0.022	0.126	1.812 (0.845–3.886)
Multivalvular disease	0.004	0.284	1.275 (0.818–1.989)
Tricuspid annular plane excursion, mm	0.002	<0.001	0.926 (0.890–0.963)

OR indicates odds ratio.

**Table 3. Details of the Management Strategy in Patients Referred to Different Treatments by the HT**

Characteristic	Cardiac surgery	Percutaneous intervention	Hybrid intervention
No. of patients with data	230	516	61
Mean age, y	68	79	77
Female sex, n (%)	91 (39.6)	288 (55.8)	22 (36.1)
Key baseline characteristics, n (%)			
Ischemic heart disease	98 (42.6)	299 (57.9)	49 (80.3)
Acute coronary syndrome	8 (3.5)	33 (6.4)	6 (9.8)
Previous cardiac surgery	21 (9.1)	91 (17.6)	19 (31.1)
Oncologic or hematologic disease	13 (5.7)	43 (8.3)	9 (14.8)
Multivalvular disease	69 (30.0)	132 (25.6)	23 (37.7)
Management strategy after HT, n (%)			
Crossover to conservative management	25 (10.9)	24 (4.7)	2 (3.3)
Crossover to other interventional management	2 (0.9)	2 (0.4)	5 (8.2)
HT intervention during hospitalization	60 (26.1)	310 (60.1)	40 (65.6)
Mean time to treatment, d	55	25	21
Intervention, n (%)			
Valve surgery with prosthesis implantation	180 (78.3)	2 (0.4)	7 (11.5)
Valve surgery without prosthesis implantation	16 (7.0)	...	1 (1.6)
TAVI with surgical trans-apical, trans-aortic or trans-subclavian access	...	...	45 (73.8)
Percutaneous transfemoral TAVI	1 (0.4)	402 (77.9)	2 (3.3)
Percutaneous mitral valve repair	...	21 (4.1)	...
Percutaneous balloon valve dilation	...	15 (2.9)	...
Other transcatheter prosthetic valve implantation	...	1 (0.2)	...
CABG	41 (17.8)	...	4 (6.6)
PCI	...	52 (10.1)	14 (23.0)
Cardiac stimulation therapy	1 (0.4)	8 (1.6)	1 (1.6)
Staged interventions	5 (2.2)	64 (12.4)	13 (21.3)

CABG indicates coronary artery bypass graft; HT, heart team; PCI, percutaneous coronary intervention; and TAVI, transcatheter aortic valve implantation.

American College of Cardiology Transcatheter Valve Therapy using the online TAVI in-hospital mortality risk calculator (<https://tools.acc.org/TAVIrisk/#/content/evaluate/>) was 4.8%, and the observed mortality was 0.7%.

Patients referred to hybrid interventions received the recommended intervention in 96.7% of cases. No patient died in this group, so the observed mortality was significantly lower than that predicted by both the EuroSCORE II ( $P=0.017$ ) and STS-PROM ( $P=0.071$ ) (Figure 3). Similar results were observed in “as treated” analysis: no death was observed in the hybrid treatment versus 8.7% by the EuroSCORE II ( $P=0.023$ ) and 5.2% by the STS-PROM ( $P=0.086$ ).

## DISCUSSION

How to ensure the best management of patients with VHD represents a daily clinical challenge. The HT session is a unique opportunity where different clinicians

share their competencies and experience to achieve a “patient-centered” decision. Yet, solid scientific data supporting HT are lacking. In the present study, we report our experience with HT-based management in >1000 patients with VHD with high clinical complexity. The reported findings suggest that HT-based management in VHD is (1) feasible because the vast majority of patients were treated according to the HT recommendations and (2) facilitates a “patient-tailored” intervention selection because a wide range of surgical, percutaneous, or hybrid interventions were offered, obtaining favorable mortality rates. These observations support the implementation of HT-based decision-making processes for patients with VHD.

During the past 2 decades, the possible value of a multidisciplinary approach in evolving fields, such as modern oncology and contemporary cardiovascular medicine, has been emphasized. The notion of HT in cardiology decisions stemmed by the increasing availability of different treatment options for patients with

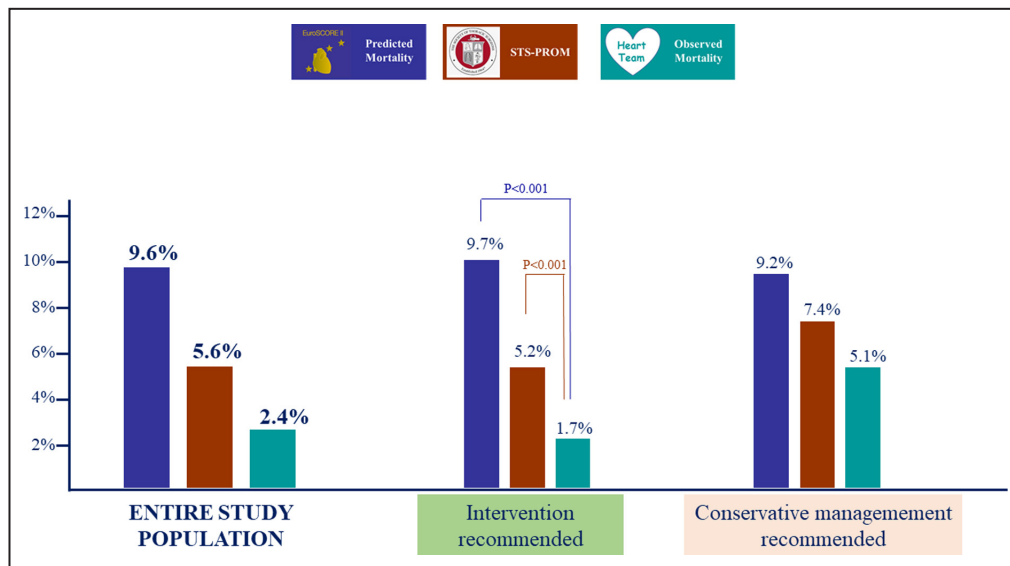
**Table 4. Predictors of Early Death**

Characteristic	P univariate	P multivariate	OR (95% CI)
Age	0.001	0.343	1.022 (0.977–1.070)
Chronic kidney disease	0.012	0.174	1.726 (0.786–3.791)
Aortic stenosis	0.043	0.054	2.348 (0.986–5.590)
Multivalvular disease	0.006	0.583	0.783 (0.326–1.877)
Ischemic heart disease	0.013	0.995	1.002 (0.437–2.298)
NYHA class	0.038	0.641	1.336 (0.395–4.514)
LVEF, %	<0.001	0.030	0.964 (0.933–0.996)
Frailty	<0.001	0.113	1.996 (0.850–4.689)
Pulmonary artery systolic pressure, mm Hg	<0.001	0.002	1.041 (1.014–1.068)
High-priority intervention	<0.001	0.008	3.604 (1.398–9.289)
Conservative management recommendation	0.011	0.001	11.077 (2.537–48.363)

LVEF indicates left ventricular ejection fraction; NYHA, New York Heart Association; and OR, odds ratio.

specific diseases. Indeed, the need of HT in cardiology was first proposed by the task force of the European Society of Cardiology/European Association of Cardio-Thoracic Surgery (ESC/EACTS) 2010 Myocardial Revascularization Guidelines<sup>9</sup> with the aim of achieving joint decisions regarding myocardial revascularization modality in patients with complex IHD. In the past decade, various experiences with dedicated multidisciplinary teams were reported, mainly focusing on diseases with inherent need for different specialties (endocarditis<sup>10</sup>) or specific conditions offering novel therapeutic options (TAVI<sup>11</sup>). In contrast with recent position papers and guidelines, many hospitals do not have regular HT meetings yet<sup>12</sup> or the HT composition comprises only cardiac surgeons and interventional

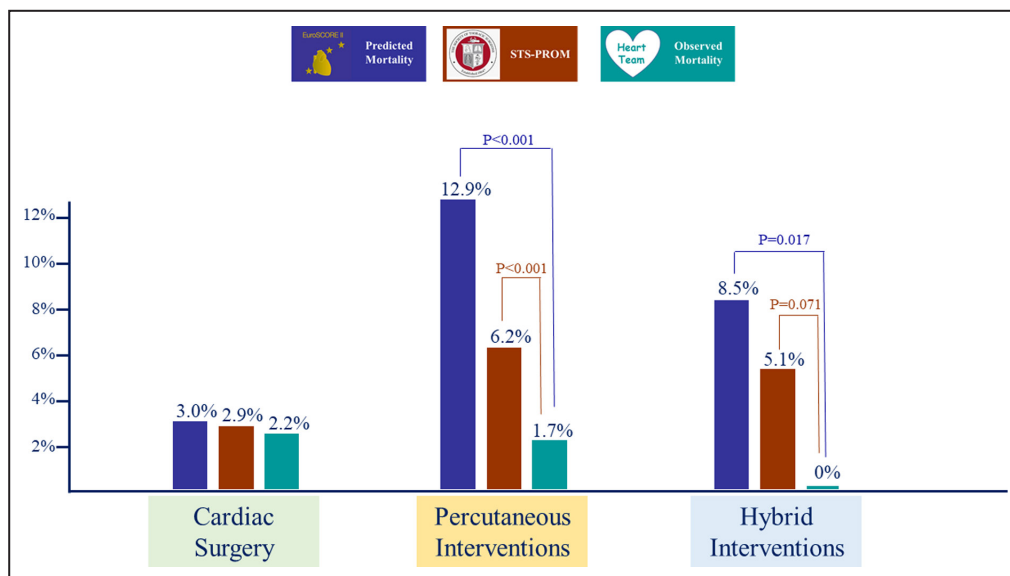
cardiologists.<sup>12</sup> This can be justified by the lack of large trials supporting HT clinical efficacy and by the perception that a multidisciplinary decision-making process may imply diagnostic and treatment delays.<sup>13</sup> In this context, at our Institution, we decided to make a step forward to promote the multidisciplinary team by offering the possibility of having daily HT sessions with formal recording into the hospital records. The daily schedule was intended as a measure to reduce treatment delays and facilitate the referring physicians in taking timely decisions. The formal recording into the hospital records was set to allow tracking the HT consultation occurrence into the patient’s clinical course. Among different subsets of cardiovascular diseases, VHD often poses challenges because of the increasing



**Figure 2. Observed and predicted (by EuroSCORE II and STS-PROM) mortality in the whole study population and in the subgroups according to heart team recommendation for intervention or conservative management.**

EuroSCORE indicates European System for Cardiac Operative Risk Evaluation; and STS-PROM Society of Thoracic Surgeons Predicted Risk of Mortality.





**Figure 3. Observed and predicted (by EuroSCORE II and STS-PROM) mortality in the subgroups according to recommended intervention type.**

EuroSCORE indicates European System for Cardiac Operative Risk Evaluation; and STS-PROM Society of Thoracic Surgeons Predicted Risk of Mortality.

recognition of comorbidity relevance and evolving interventional options. These issues were confirmed by the present study, where a “selected” cohort of patients with VHD with high clinical complexity and multiple therapeutic opportunities was submitted to HT consultation. In particular, VHD accounted for >66% of patients referred to HT consultations during the study period, noncardiac comorbidities were extremely common (chronic pulmonary disease in 34%, chronic kidney disease in 29%, oncological or haematological diseases in 9.3%), and final treatments embraced a broad spectrum of surgical, percutaneous, and hybrid interventions. Some previous studies reported the results of HT-based management in patients with specific VHD types so that smaller study populations were recruited, homogenous VHDs were discussed, and fewer management options were evaluated.<sup>14–22</sup> On the contrary, in the present study we enrolled a broad spectrum of hospitalized patients with VHD (including multivalvular disorders in one-third and concomitant IHD in half of the population). In such a real-world scenario, an interventional treatment was suggested by HT in 80% of patients and was effectively carried out in 75% of them. The applied interventions embraced a wide range of treatment options comprising the correction of a main valve dysfunction in 69% of the entire cohort and the selection of just nonvalvular interventions in some patients (mainly with IHD and unstable presentation). Of note, not only surgical or percutaneous interventions but also staged and hybrid management came out of HT discussions. This is particularly

noteworthy as hybrid interventions constitute a novel option for some patients with VHD,<sup>23–25</sup> and a multidisciplinary discussion is ideal for their appropriate planning.

Moving from practice description to outcomes, in this study, the HT discussed patients with VHD characterized by high surgical risk (9.4% EuroSCORE II, 5.6% STS-PROM) in which treatment decisions require careful risk/benefit balancing and personalized managements are particularly desirable. Because of the absence of possible reliable control groups, we compared the observed mortality with the mortality predicted by 2 highly validated surgical risk scores.<sup>26–28</sup> The most relevant finding is that early mortality was significantly lower than that predicted by most efficient scores in the case of systematic surgical VHD correction. This was true not only when considering the whole study population but also when considering each treatment category. Observed mortality with cardiac surgery was numerically lower, whereas mortality in HT-driven percutaneous and hybrid treatment subgroups was striking (and statistically significant) lower than expected. This is particularly interesting if we consider the higher estimated surgical scores in these latter subgroups. Although mortality prediction of patients undergoing nonsurgical treatments is still evolving and surgical scores might have major limitations in this setting,<sup>29</sup> these results support the efficacy of HT in referring the patients to the appropriate treatment. Indeed, it seems that patients with acceptable risks have been identified and treated by cardiac surgery, whereas other patients (instead of undergoing surgery with predicted hazards)

were referred to tailored management that often included transcatheter valve interventions and (in the case of co-existent IHD) percutaneous coronary revascularizations. Importantly, the HT recommended conservative management for a notable 20% of patients with VHD. The high number of such patients probably reflects the fact that only hospitalized patients were included and that the study was conducted in a large tertiary referral center serving as the hub also for many advanced noncardiac diseases. Clinical conditions such as previous stroke or infectious diseases predicted conservative management because the valve treatment was judged as noncritical for the immediate clinical evolution. Other features associated with conservative management included conditions (ie, hemodynamic instability, especially in the absence of aortic stenosis) that made interventional options limited. Not surprisingly, conservative management was independently associated with increased mortality. Yet, it should be emphasized that the causal relation between the lack of treatment and mortality risk cannot be estimated from the association observed in the present study because the HT decision might have been influenced by factors (infectious disease or hemodynamic instability) that might by themselves increase the mortality risk of hospitalized patients. Nevertheless, the observed early mortality was significantly lower than that expected in the case of systematic surgical treatment. These data support the concept that not all patients with high surgical risk were denied treatment and highlight this subset of patients with VHD as a potential target for treatment improvements.

## Limitations

The present study has some major limitations. The study design is observational, and no comparative arm was selected. This was the result of the impossibility of finding reliable historical comparisons because in the prior period at our hospital, no electronic resource to select patients with VHD requiring collegial discussion was available before the dedicated HT form was designed.

The 2 scores we selected to predict risk are perfectly balanced for cardiac surgery, and the lower-than-expected mortality might theoretically be explained by the selection of percutaneous interventions such as TAVI or percutaneous coronary intervention in patients with higher surgical risk. Yet, the performance of percutaneous coronary intervention in the setting of high surgical risk is usually not risk free,<sup>30</sup> and the risk for transcatheter interventions as predicted by the available dedicated score<sup>31</sup> was not negligible. In particular, patients treated by TAVI in the present study had a survival that compared favorably not only with that predicted by surgical scores but also with that predicted by a validated TAVI-dedicated score.<sup>31</sup>

Finally, we recognize that, during the study period, VHD management had an articulated evolution where the individual effect of HT on outcomes is difficult to dissect. Other reasons, such as enhanced imaging, improved preoperative/postoperative care, expanded catheter-based options, and surgical technique refinements, might have played a role in determining the observed outcomes. Among these, we were able to notice that, over time, recommendations to surgery were stable, whereas those for percutaneous interventions were significantly raised. In this regard, according to our experience, the HT also played a key role in facilitating the introduction of all these novelties into the broad context of clinical care for hospitalized patients with VHD.

## CONCLUSIONS

The results of the present single-center, observational study suggest that HT-based management of patients with complex VHD is feasible and allows referral to a wide spectrum of interventions with promising early clinical results.

## ARTICLE INFORMATION

Received November 9, 2021; accepted March 7, 2022.

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### Acknowledgments

We thank the physicians of the Department of Cardiovascular Sciences for their contribution to heart team sessions preparation and for their daily effort to translate into practice the heart team recommendations. Furthermore, the data management benefited from the invaluable help of Diana Verdirosi (who was responsible for database organization and statistical analyses). Finally, a special thanks to Dr Silvia Malara: as a medical student, she helped with enthusiasm to realize the present study and based her final thesis on its preliminary data.

### Sources of Funding

None.

### Disclosures

Drs Burzotta, Trani, Romagnoli, and Aurigemma received speakers' fees from Abbott, Medtronic, Terumo, and Abiomed. Dr Leone received speaking honoraria from St. Jude Medical/Abbott, Medtronic, Abiomed, and Bracco Imaging. The other authors have no conflicts of interest.

### Supplemental Material

Tables S1–S2

Figure S1

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## **SUPPLEMENTAL MATERIAL**



**Table S1. Comorbidities definitions**

<b>Comorbidity</b>	<b>Definition</b>
Chronic kidney disease	For patients not on chronic dialysis: glomerular filtration rate <60 ml/min
Peripheral artery disease	Claudication intermittens, previous or planned intervention on the abdominal aorta or limb arteries
Carotid artery disease	Carotid occlusion or >50% stenosis
Chronic pulmonary disease	Use of oxygen, bronchodilators or steroid for lung disease
Neurologic disability	Any diagnosed neurologic disease severely affecting ambulation or day-to-day functioning
Systemic inflammatory and/or autoimmune disease	Any disease requiring chronic anti-inflammatory drug therapy
Oncologic or haematologic disease	Any active oncologic or hematologic disease requiring specific medical or surgical therapy
Infective disease	Any infective disease requiring antibiotic, antiviral or anti-fungal therapy
Ischemic heart disease	Significant coronary lesions at pre-HT coronary angiography or previous myocardial infarction or previous (percutaneous or surgical) myocardial revascularization
Coronary stenosis	≥50% angiographic stenosis for unprotected left main lesions, or ≥75% angiographic stenosis for non-left main lesions, or angiographically-intermediate lesions with positive (≤0.80) fractional flow reserve

**Table S2. Temporal trends for treatment recommendation and mortality during the study**

	<b>Percutaneous treatment</b>	<b>Surgical treatment</b>	<b>Early mortality</b>	<b>Surgical treatment mortality</b>
<b>1<sup>st</sup> quarter</b>	3.2%	20.1%	4.6%	1.5%
<b>2<sup>nd</sup> quarter</b>	4.0%	18.5%	2.5%	2.7%
<b>3<sup>rd</sup> quarter</b>	10.2%	19.5%	3.1%	0.0%
<b>4<sup>th</sup> quarter</b>	10.3%	19.0%	4.8%	0.0%
<b>P-value</b>	<b>p&lt;0.01</b>	p=0.974	p=0.600	p=0.558

Figure S1. Structured electronic form for Heart Team meeting.

 Fondazione Policlinico Universitario A. Gemelli Università Cattolica del Sacro Cuore		Fondazione Policlinico Universitario Agostino Gemelli Sede Legale L.go F. Vito 1-00168 Roma Codice Fiscale e P.IVA 13109681000 DIPARTIMENTO DI MEDICINA CARDIOVASCOLARE
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Cognome	Nome	D. nascita	Sesso
C.Fiscale	C.Sanitario	Telefono	Regime Ric
Nosografico	Codice SDO	U.O.	

## Valutazione Heart Team

**Dati Antropometrici**  
Altezza cm Peso kg Body Mass Index kg/m<sup>2</sup> Body Surface Area m<sup>2</sup>

**Diagnosi Cardiovascolare**

**Fattori Di Rischio Cardiovascolare**

**Altre Informazioni**  
EF % NYHA Provenienza Medico di riferimento

**Score, Copatologie e Progressi**  
EUROSCORE II % STS

**Conclusioni**

Dopo discussione collegiale l'Heart Team formula la seguente indicazione:  
**Indicazione Finale:**

*data, ora della discussione, nome del medico responsabile*

The figure shows the structured electronic form for Heart Team meeting which was adopted at our Institution during the study period.