Initial clinical experience with hand – held device (Thrombocheck©) for the detection of bileaflet prosthetic valve malfunction.

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Abstract

Introduction

Early recognition of subclinical prosthetic valve (PV) malfunction may allow for early treatment and avoidance of serious complications. Echocardiography cannot be applied on a daily basis. Therefore a hand – held device (Thrombocheck©) capable of detecting subtle changes in the acoustic sounds of prosthetic valve has been developed for routine home monitoring of heart valve function. We report our initial clinical experience with this device.

Methods

Seventy one consecutive patients with one or more bileaflet prosthetic mechanical valves at any position were assessed both by transthoracic echocardiography (TTE), fluoroscopy and by Thrombocheck©. These patients attended our clinic for either routine echocardiography (62 patients) and for detection of prosthetic valve malfunction (9 patients).

The Thrombocheck© was held for one minute in subxhiphoid position perpendicular to the patient, and provided any of the 3 indications: OK – normal function of the PV; Warning – after 3 repeat measurements (1 min each) - abnormal function of the PV; No signal – the not identified by the device.

Results

The study group had in total 82 bileaflet valves: 47 mitral, 31 aortic and 4 tricuspid.

There were 8 (10%) patients with "no signal" indication. Of the remaining 63 patients, there were 10 patients (18.9%) with WARNING alarm in whom 8 had echocardiographic and fluoroscopic evidence of current abnormal leaflet motion, one patient has a recent history of abnormal leaflet motion, and one patient had no evidence of prosthetic valve malfunction. The sensitivity and specificity for detecting abnormal PV malfunction were 90% and 98%, respectively.

Conclusion

Thrombocheck© had an excellent sensitivity and specificity for the detection of prosthetic valve malfunction in a cohort of patients with bileaflet mechanical prosthetic heart valves.

Introduction

Mechanical prosthetic heart valves carry a yearly complication rate of 2-3%, including malfunction due to thrombosis and tissue ingrowth (1). These complications are associated with high morbidity and mortality rate. Early recognition of subclinical prosthetic valve malfunction may allow early treatment and avoidance of serious complications (hemodynamic instability or thromboembolism). Echocardiography, which is used for routine follow up of patients with prosthetic valves, cannot be applied on a daily basis and requires skilled echocardiographers. Several reports showed typical pattern of closing of the prosthetic valves on real-time sound spectroanalysis at normal condition and with dysfunction of the prosthetic valves (2-5). Fritzsche et al showed that the acoustic sounds of the prosthetic valve remain constant under similar conditions and that patients' valve signals didn't change significantly over 6 month period (6). Animal studies showed that frequent control of the heart valve sounds can detect very subtle changes in the integrity of the heart valve sounds before they lead to hemodynamic or thromboembolic consequences, readily detectable by echocardiography (7).

Therefore a hand – held device (Thrombocheck©) has been developed for routine home monitoring of heart valve function. The individual signature of the heart valve sound is computed from its acoustic information. It detects valve acoustic sounds in the region of 11 kHZ, and is able to detect subtle changes in the acoustic sounds.

We report the results of routine use of this new hand – held device in clinical practice.

Methods

Seventy one consecutive patients with at least one bileaflet prosthetic mechanical valve at any position who attended our clinic for either routine echocardiography or for detection of valve malfunction, were assessed both by echocardiography and by hand–held device (Thrombocheck©). Transthoracic echocardiography was done with Sonos 5500 equipment (Philips, Andover, MA, USA) with second harmonic capabilities. All the prosthetic valves were carefully assessed both for hemodynamics and for leaflet motion in multiple views, as previously reported (8). Transesophageal echocardiography (TEE) was done as needed with the same echocardiographic machine and a multiplane 3.7/5 MHz probe.

Prosthetic valve malfunction was suspected when echocardiography showed high gradients across the prosthetic valve or increased (>25%) gradient across the prosthetic valve comparing the past examination, or inability to demonstrate full range motion of the two discs. In any case of suspicion of valve dysfunction the patient was referred for fluoroscopy and/or TEE.

There were no exclusion criteria for testing the Thrombocheck©. In patients with 2 prosthetic valves with an immobilized leaflet in one of them, the analysis of diagnostic accuracy of the device was applied to this very valve only. In the analysis of patients after mitral valve replacement we included only the double disc mitral valve.

The Thrombocheck© was set for double disc sounds. We used the same Thrombocheck© device for all patients.

The Thrombocheck© was held for one minute in subxhiphoid position perpendicular to the patient, which was lying in a recumbent position. There were 3 optional textual results on the screen of the device:

OK – indicated normal function of the prosthetic valve.

Warning – after 3 repeat measurements (1 min each) indicated abnormal function of the prosthetic valve.

No signal – the Thrombocheck© did not identify valve sounds.

Results

Seventy one patients were enrolled (25 male, 46 female), aged 58.5 ± 13.3 years old (range 25 years – 82 years). These patients had in total 82 bileaflet valves: 47 mitral, 31 aortic and 4 tricuspid. (Table 1).

The annular diameters of the mitral, aortic and tricuspid valves ranged from 25-31 mm (median 27 mm), 19-25 mm (median 21 mm), and 27-33 mm, respectively. The valve models included were St Jude Medical (St. Paul, Minnesota, USA), CarboMedics (Sulzer Carbomedics, Austin, Tx) and Sorin Bicarbon (Sorin Biomedica, Saluggia, Italy). There were 8 patients with "No signal" indication (one of them was after isolated TVR). Out of the remaining 63 patients, there was a WARNING alarm in 10 (18.9%) with the following clinical and echocardiographic findings: 8 patients had evidence of current abnormal leaflet motion (Table 2); one patient had no evidence of prosthetic valve malfunction, and one patient was two months after thrombolysis therapy due to valve dysfunction and high gradient across the prosthetic valve. This patient was readmitted several months later with obstructive valve thrombosis, and was reoperated. The operative specimen showed combined thrombus and pannus formation. Six patients with abnormal leaflet motion were tested with the device following anti-thrombotic or thrombolytic treatment (Table 2). In 4 patients with successful thrombolysis, the Thrombocheck© showed normal PV function ("OK"). In one patient with anti-thrombotic treatment and chronic abnormal leaflet motions there was a “No signal” indication. In one patient with recurrent hospital admissions because of abnormal leaflet motions and known high pressure gradient on the mitral valve due to prosthesis-patient mismatch, the Thrombocheck© showed WARNING after treatment, whereas the fluoroscopy showed normal discs movement, and the pressure gradient across the mitral valve returned to baseline.

There was one patient after tricuspid valve replacement with chronic abnormal leaflet motion in whom the Thrombocheck© indicated OK.

Table 3 summarizes the testing results of the Thrombocheck© and the impact of valve position on its diagnostic accuracy. There were only one false positive test and one false negative test. After exclusion patients with ”No signal” indication, the Thrombocheck© had a sensitivity and specificity of 90% and 98%, respectively, for the detection of prosthetic valve malfunction. The subgroup analysis according to valve position indicates sensitivity of 100% and specificity of 97% for patients with MVR and 100% specificity and 95% sensitivity for patients with AVR.

Discussion

In the current study the hand – held - Thrombocheck© had an excellent sensitivity and specificity (90% and 98%) for the detection of prosthetic valve malfunction in a cohort of patients with bileaflets prosthetic heart valves, both for the mitral and the aortic position. A high diagnostic accuracy is an invaluable prerequisite for the daily implementation of the thrombocheck©. We should not miss valve malfunction at one hand, and false alarm indications are undesirable as well. The high sensitivity of the thrombocheck© provides assurance for both the patients and their physicians.

Two of our patients demonstrate the usefulness of the Thrombocheck©. In one patient (number 8 in Table 2) the Thrombocheck© provided various indications which paralleled with the leaflet motion: it showed WARNING early after thrombolysis, and then OK after 7 months. A few months later it could not be calibrated for this very patient for bileaflet valve, and a repeated obstructive valve thrombosis was diagnosed. The other patient (number 9 in Table 2) with moderately elevated aortic valve gradients (peak 50 mmHg, mean 30 mmHg) in a 19 mm CarboMedics prosthesis, the Thrombocheck© indicated WARNING. Fluoroscopy showed only 30 degree limitation of the combined travel angle of the valve. These examples represent the high sensitivity of the Thrombocheck© for the detection valve malfunction, even in asymptomatic patients. This early recognition of subclinical prosthetic valve malfunction may allow early treatment before development of serious complications which may lead to hemodynamic instability, thromboembolism and death. It may also detect valve thrombosis at a stage where the thrombus burden will not be associated with high complication rate when thrombolysis is applied (9).

Follow up of patients with valve malfunction who were treated (by either antithrombotic therapy or intensified anticoagulation) showed resolution of the WARNING indication in four patients. These resolutions of the WARNING indication further strengthens the reliability of the Thrombocheck©. The device may be especially suitable for patients with a prior history of prosthetic valve malfunction. These patients have a higher likelihood of additional episodes, which may reach 23% (10).

Thrombocheck© is planned for individual use and a previous study reported the use of individual devices for patients without reporting any difficulty in detecting valve signal (7). In 10% of our patients the Thrombocheck© indicated “No signal”. We do not know if this indication reflects the limitation of the Thrombocheck©, valve dysfunction, or (probably) the use of the same hand–held device (same acoustic fingerprint) for all patients.

Study limitations:

The number of patients in the current study is limited. In addition, we used the same hand – held device for all patients. It is expected that if patients receive a personal device, and this device will initially be checked for appropriate valve function, the accuracy of the device will further improve. Moreover, those patients who will initially show "no signal" will not be offered the device.

Conclusion:

We report, for the first time, initial experience with the hand – held device - Thrombocheck© in the clinical practice. It is a simple and comfortable device for home monitoring with an excellent sensitivity and specificity for the detection of prosthetic valve malfunction. Nevertheless, we believe that it should serve as a screening tool, for assurance at one hand and

alert at the other hand, but it cannot replace echocardiography or fluoroscopy in the thorough evaluation of prosthetic valves.

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Table 1: Valve position.

Valve position	Number of patients
Isolated AVR	21
Isolated MVR	34
AVR + MVR*	10
MVR + TVR**	5
TVR	1

AVR – aortic valve replacement, MVR – mitral valve replacement, TVR – tricuspid valve replacement.

*Two patients with single disc mitral valves.

** Two patients with biological tricuspid valves.

Table 2: Characteristic, therapy and outcome of patient's with abnormal leaflet motions.

Patient number	Valve position	Valve model	Fluoroscopic findings	Thrombocheck findings before treatment	Treatment: Antithrombotic /intensify anticoagulation	Valve function after treatment	Check up after treatment
1	Aortic	SJM	One leaflet stuck at closed position	Warning	Heparin and Thrombolysis	Normal	OK
2	Mitral	CM	One leaflet stuck at closed position.	Warning	Heparin and Thrombolysis	Normal	OK
3	Aortic	SJM	Incomplete opening of a leaflet	Warning	Heparin	Abnormal	Repeat measure ment X3
4	Aortic	NA	Incomplete opening of both leaflets	Warning	Heparin	Normal	NA
5	Aortic	CM	Incomplete opening of one leaflet	Warning	Heparin	Normal	OK
6	Mitral	CM	One leaflet stuck at closed position.	Warning	Heparin and Thrombolysis	Normal*	Warning
7	Aortic	CM	One leaflet stuck at closed position.	Warning	Heparin and Thrombolysis	Normal	OK
8	Mitral	SB	NA	Warning	High dose anticoagulation and aspirin	Abnormal	**
9	Aortic	CM	Incomplete opening of both leaflets (15-20^0 missing for each leaflet)	Warning	High dose anticoagulation and aspirin	Under evaluation	

CM – CarboMedics. NA – Not available. SB – Sorin Bicarbon; SJM - St. Jude Medical;. * This patient had recurrent abnormal leaflet motions

** OK after 7 months, device could not be calibrated for double disc at later follow-up – with repeated valve obstruction.

Table 3: Effect of valve position on diagnostic accuracy of the Thrombocheck©*

	All patients	MVR	AVR	TVR
Number of patients	71	47	31	4
No signal indication (%)	8 (10)	6 (13)	5 (16)	1 (25%)
Patients excluded from analysis due to abnormality in an additional valve		3 **	0	0
Patients analyzed for diagnostic accuracy	63	38	26	3
Sensitivity (%)	9/10(90)	3/3 (100)	6/6 (100)	0/1 (0%)
Specificity (%)	52/53(98)	34/35 (97)	19/20 (95)	2/2 (100%)

AVR – mitral valve replacement; MVR – mitral valve replacement; TVR – tricuspid valve replacement.

*The statistical analysis was done after exclusion patients with “No signal” indication.

** The associated abnormal valve was aortic in 2 patients and tricuspid in 1 patient.