Doppler Assessment of Mechanical Aortic Valve Prostheses: Effect of Valve Design and Size of the Aorta

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Background and aim of the study: **Discrepancies between Doppler and catheter gradients have been reported for bileaflet aortic valve prostheses. Whether modifications in geometric design of newly developed bileaflet valves lead to a different Doppler-catheter gradient relationship has not been evaluated. Variable results have been reported for tilting-disc prostheses. In addition, the effect of aortic size on the Doppler-catheter gradient relationship remains unclear.**

Methods: **Various sizes of On-X and Edwards Mira (identical with Sorin Bicarbon) bileaflet valves and Sorin Allcarbon tilting-disc aortic valves (19-25 mm) were studied in a pulsatile flow model. Doppler and catheter gradients were measured simultaneously. Aortic diameters between 1.8 and 4 cm were evaluated.**

Results: **Correlation between Doppler and catheter gradients was excellent (r = 0.98-0.99 for peak and mean gradients), but in bileaflet valves Doppler significantly overestimated the corresponding catheter gradients as reflected by slopes of the regression lines (1.57-1.8). In the range of relevant gradients ≥10 mmHg, Doppler exceeded catheter gradients by 40 ± 17% (peak) and 39 ± 16% (mean) in Mira valves, and by 46 ± 19% (peak) and 43 ± 14% (mean) in On-X valves. In the Sorin tilting-disc valve, Doppler accurately reflected catheter gradients (slopes of regression lines 1.05-1.14). The aortic diameter significantly influenced results in only tilting-disc valves, but in absolute terms the effect was clinically less relevant.**

Conclusion: **Discrepancies between Doppler and catheter gradients are common to all bileaflet valves, regardless of their specific geometric design, whereas tilting-disc valves must be considered individually. The influence of aortic size on the Doppler-catheter gradient relationship appears clinically to be less relevant in prosthetic valves.**

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Doppler echocardiography has become the most widely used tool for the assessment of prosthetic heart valve function. Nevertheless, the evaluation of prosthetic valves by ultrasound remains challenging because of specific problems. Although Doppler gradients across stenotic native aortic valves accurately reflect the pressure drop as determined by catheter technique (1-3), significant discrepancies between Doppler and catheter gradients have been reported for some prosthetic valves (4-6). Knowledge of these phenomena is essential in order to avoid misdiagnosis of prosthetic valve malfunction. To date, a considerable number of aortic valve prostheses have been evaluated, including the St. Jude Medical (4-8), CarboMedics and Duromedics bileaflet valves (9), the Starr Edwards caged-ball valve (6), and Medtronic Hall (6,7), Björk-Shiley (10,11) and Omnicarbon (8) tilting-disc valves.

Significant discrepancies between Doppler and catheter gradients have been observed for bileaflet aortic valve prostheses (4-9), while the reported Doppler-catheter gradient relationship varies for tilting-disc valves (6,10,11). Differences between Doppler and catheter gradients across bileaflet valves are caused by localized high velocities between the two leaflets and pressure recovery (4,12,13). Recently, new models of bileaflet valves have been developed whereby the manufacturers aimed to minimize the pressure drop across the valves, and this resulted in a modified geometric valve design (14-16). However, whether these differences in design may also result in a different Doppler-catheter gradient relationship has not been evaluated.

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For tilting-disc valves, both good agreement between Doppler and catheter gradients (e.g. for Medtronic Hall valves (6)) as well as significant discrepancies (e.g. for Björk-Shiley valves (10)) have been reported.

Furthermore, it has recently been suggested that the size of the receiving chamber may also influence the Doppler-catheter gradient relationship in bileaflet prosthetic valves (5). This has also been recognized in native aortic stenosis (17,18). However, whether the size of the ascending aorta does indeed play a clinically relevant role for discrepancies between Doppler and catheter measurements remains unknown.

The study aim was to investigate the Doppler-catheter gradient relationship and the influence of aortic size on that relationship in two more recently designed bileaflet valves and one tilting-disc aortic valve. The data obtained should help in the correct interpretation of Doppler measurements in these prostheses.

Materials and methods

In-vitro flow model

The modular in-vitro flow circuit used in the present study has previously been described in detail (19) (Fig. 1). The system is driven by a computer-controlled piston pump (Vivitro Inc.™) which generates stroke volumes from 10 to 100 ml. Ejection pressure can be varied from 0 to 300 mmHg, pulse rate from 30 to 120 beats per minute, and ejection time from 100 to 700 ms. Flow rate is measured with an ultrasonic flowmeter (Transonic Systems Inc.™) that was calibrated against timed collections. In the present study, the flow probe was placed between pump and prosthetic valve. Pressure taps 10 mm proximal and 50 mm distal to the stenosis were connected to electronic pressure transducers (Peter van Berg™, Hellige signal amplifier™) by fluid-filled catheters. Physiological pressures were maintained by adjusting pump characteristics, distal compliance and resistance. An aortic diameter of 4.0 cm was chosen to minimize pressure recovery (18). For a subset of valves, experiments were repeated with aortas 1.8 and 2.4 cm in diameter to study the effect of aortic size on the Doppler-catheter gradient relationship. The test section has been designed to allow optimal alignment of Doppler beam and flow across the prosthetic valve.

A water:glycerol mixture (70:30, v/v), which approximates the viscosity of blood at a temperature of 21°C (3.5 cp), served as the test fluid. Cornstarch (10 g/l) was added to facilitate Doppler measurements.

Doppler, pressure- and flow tracings were recorded simultaneously and transferred to a data acquisition system (Hellige GmbH™, PC™) for further analysis which was performed with commercially available software (Famos 3.0™).

The set-up used resulted in Doppler, flow and pressure tracings which were very similar to the in-vivo setting.

Types of heart valve prosthesis

Two types of bileaflet valve were evaluated: (i) the Edwards Mira 3600 (sizes 19-25 mm), which was structurally identical with the Sorin Bicarbon valve; and (ii) the MCRI On-X valve (sizes 21-27 mm). In addition, the Sorin Allcarbon tilting-disc valve (sizes 19-25 mm) was studied.

Test protocol

For each experimental set-up the driving pressure of the ventricle, outflow compliance and outflow resistance were varied to obtain eight different flow rates while maintaining physiological downstream pressures. Cardiac output ranged from 1.8 to 8.9 l/min. The maximum cardiac output, however, could be achieved only for the larger prosthetic valves, and not for the small valves. The pulse rate was held constant at 60 beats/min, with an ejection time ranging from 320 to 420 ms.

Doppler echocardiography

A Vingmed CFM 800 (Vingmed Sound A/S) with a Duplex probe (2.5 MHz CW-Doppler) was used for continuous-wave Doppler measurements. The ultrasound probe was coupled to the model with gel (Gerosonic™), and its position carefully adjusted to obtain the highest Doppler velocities across the prosthesis. High-quality continuous-wave Doppler trans-

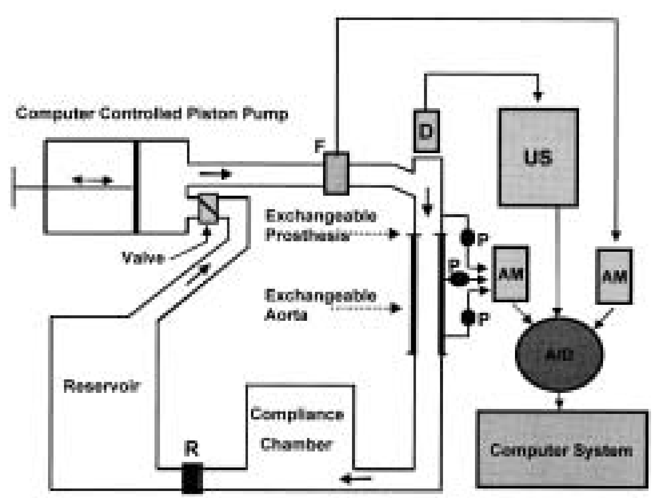


Figure 1: Diagram of the pulse duplicator. A/D: Analog-to-digital converter; AM: Amplifier; COMPL: Compliance chamber; D: Doppler probe; F: Flow probe; P: Pressure transducer; R: Resistance; US: Ultrasound device.

Table I: Edwards Mira/Sorin Bicarbon bileaflet valves: Peak and mean gradients measured by Doppler and catheter techniques.

Valve size (mm)	Peak gradient				Mean gradient			
	Doppler (mmHg)	Catheter (mmHg)	Difference (mmHg)	Difference (%)	Doppler (mmHg)	Catheter (mmHg)	Difference (mmHg)	Difference (%)
19	21.8 ± 12.4	14.6 ± 6.5	7.2 ± 5.9	41.0 ± 23.4	13.9 ± 7.9	10.0 ± 4.3	3.9 ± 4.0	32.1 ± 24.8
21	15.2 ± 9.0	12.4 ± 6.0	2.9 ± 3.1	14.8 ± 13.9	10.3 ± 5.9	7.7 ± 3.6	2.5 ± 2.4	21.8 ± 13.2
23	8.9 ± 5.4	7.2 ± 3.2	1.7 ± 2.3	11.5 ± 24.5	5.7 ± 3.4	4.6 ± 1.9	1.1 ± 1.6	10.2 ± 20.0
25	6.7 ± 3.4	4.8 ± 1.8	1.9 ± 1.7	28.2 ± 25.2	4.2 ± 2.1	3.1 ± 1.2	1.1 ± 0.9	28.6 ± 17.2

valvular velocity tracings were collected. The systolic time-velocity integral was calculated using the onboard quantitation package and manual tracing. For each measurement the average of three beats was taken. Peak instantaneous pressure gradients (Δp_{peak}) were calculated according to the simplified Bernoulli equation:

$\Delta p_{peak} = 4 \times V_{max}^2$,

where V_{max} is the maximum transvalvular velocity as obtained by continuous-wave Doppler. The mean pressure gradient was derived by averaging instantaneous pressure gradients over the ejection period using the on-board quantitation package.

Calculations based on direct flow and pressure measurements

Mean transvalvular flow was determined by integrating the area under the flow curve and dividing it by the measured systolic ejection time. The mean pressure gradient was calculated by integrating the difference between ventricular and aortic pressure throughout systole and dividing it by the ejection time.

Statistical analysis

Results were expressed as mean ± SD. The relationship between Doppler and catheter peak and mean pressure gradients was assessed by linear regression analysis. Pearson correlation coefficients were calculated.

Results

Doppler and catheter gradient comparison

Bileaflet valves

In bileaflet valves, the correlation between Doppler and catheter gradients was excellent (r = 0.95 to 0.99 for peak gradients and r = 0.98 to 0.99 for mean gradients; Fig. 2; Tables I and II). However, peak and mean Doppler gradients significantly exceeded peak and mean catheter gradients as measured 50 mm downstream from the valve. In the range of relevant gradients of ≥10 mmHg, peak Doppler gradients exceeded peak catheter gradients by 39 ± 17% in the Edwards Mira valve, and by 46 ± 19% in the On-X valve, on average. Mean Doppler gradients exceeded mean catheter gradients by 39 ± 17% in Edwards Mira and by 43 ± 14% in On-X valves. Discrepancies between peak Doppler and catheter gradients were greatest in the smallest valves, and reached maxima of 16 mmHg in the 19 mm Edwards Mira valve and 21 mmHg in the 21 mm On-X valve.

The Doppler-catheter gradient relationship was very similar in On-X and Edwards Mira prostheses, despite differences in their specific designs (Fig. 2; Tables I and II). Overestimation of catheter gradients by Doppler was slightly more pronounced in On-X valves (slopes of the regression lines 1.8 and 1.74 for peak and mean gradients, respectively) as compared to Edwards Mira valves (slopes of 1.59 and 1.57 for peak and mean gradients, respectively).

Table II: On-X bileaflet valves: Peak and mean gradients measured by Doppler and catheter techniques.

Valve size (mm)	Peak gradient				Mean gradient			
	Doppler (mmHg)	Catheter (mmHg)	Difference (mmHg)	Difference (%)	Doppler (mmHg)	Catheter (mmHg)	Difference (mmHg)	Difference (%)
21	21.0 ± 13.0	13.7 ± 6.1	7.2 ± 7.2	41.7 ± 30.8	13.6 ± 7.9	8.8 ± 4.6	4.7 ± 3.4	49.1 ± 11.9
23	12.3 ± 6.5	9.0 ± 4.0	3.2 ± 2.6	31.1 ± 13.7	7.8 ± 3.9	5.8 ± 2.4	2.0 ± 1.6	29.2 ± 16.5
25	7.3 ± 3.5	6.2 ± 2.7	1.1 ± 0.9	16.0 ± 8.4	5.2 ± 2.8	4.2 ± 1.9	1.0 ± 0.9	18.5 ± 17.0
27	5.3 ± 2.7	5.1 ± 2.6	0.2 ± 0.2	3.2 ± 6.1	4.3 ± 1.4	3.2 ± 1.2	0.1 ± 0.2	2.4 ± 3.8

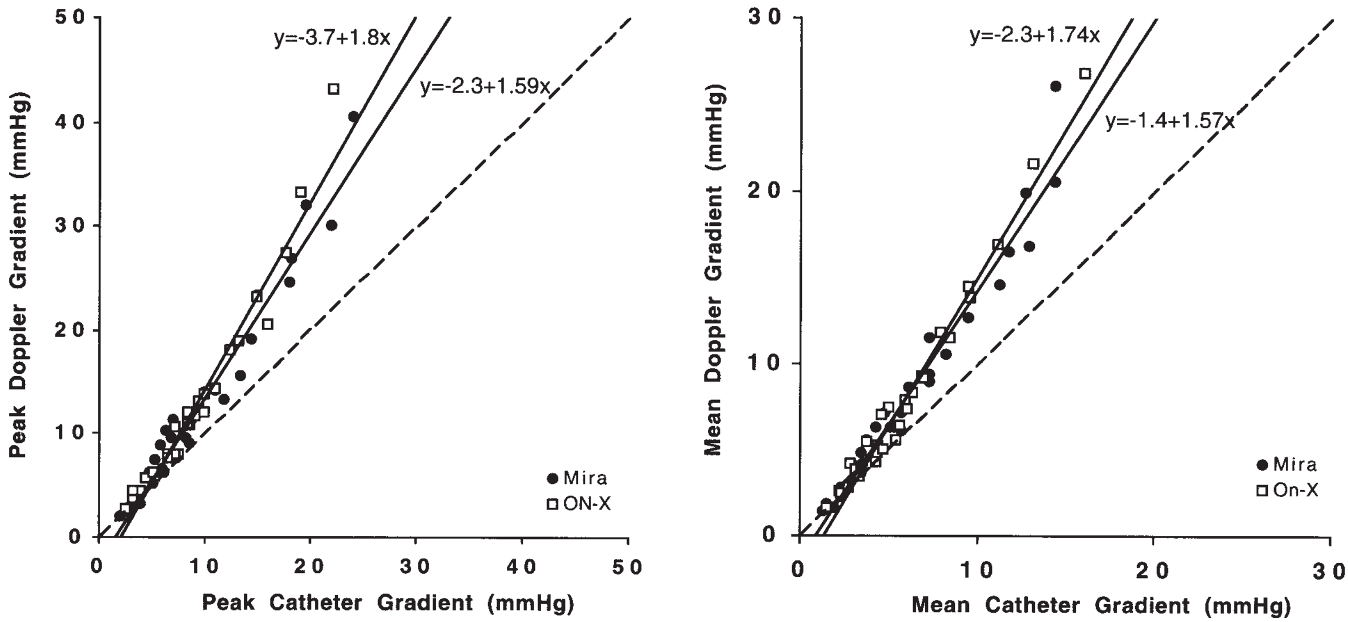


Figure 2: Peak and mean Doppler gradients versus peak and mean catheter gradients in On-X and Edwards Mira bileaflet prostheses.

Sorin tilting-disc valve

In the Sorin tilting-disc valve, the correlation between Doppler and catheter gradients was also excellent (r = 0.99; Fig. 3; Table III). However, the slopes of the regression lines varied from 1.14 for peak gradients to 1.05 for mean gradients, and were therefore close to the line of identity. In the range of catheter gradients ≥10 mmHg, peak Doppler gradients exceeded peak catheter gradients only slightly by 4.6 ± 3.0 mmHg, and mean Doppler gradients exceeded mean catheter gradients by only 0.6 ± 1.3 mmHg. The pressure drop across this valve was more pronounced than across the bileaflet valves, which has been reported previously (14,20-24).

Effect of aortic size

Bileaflet valves

In bileaflet valves, the size of the aorta did not significantly influence the Doppler-catheter gradient relationship. Figure 4A shows measurements in the

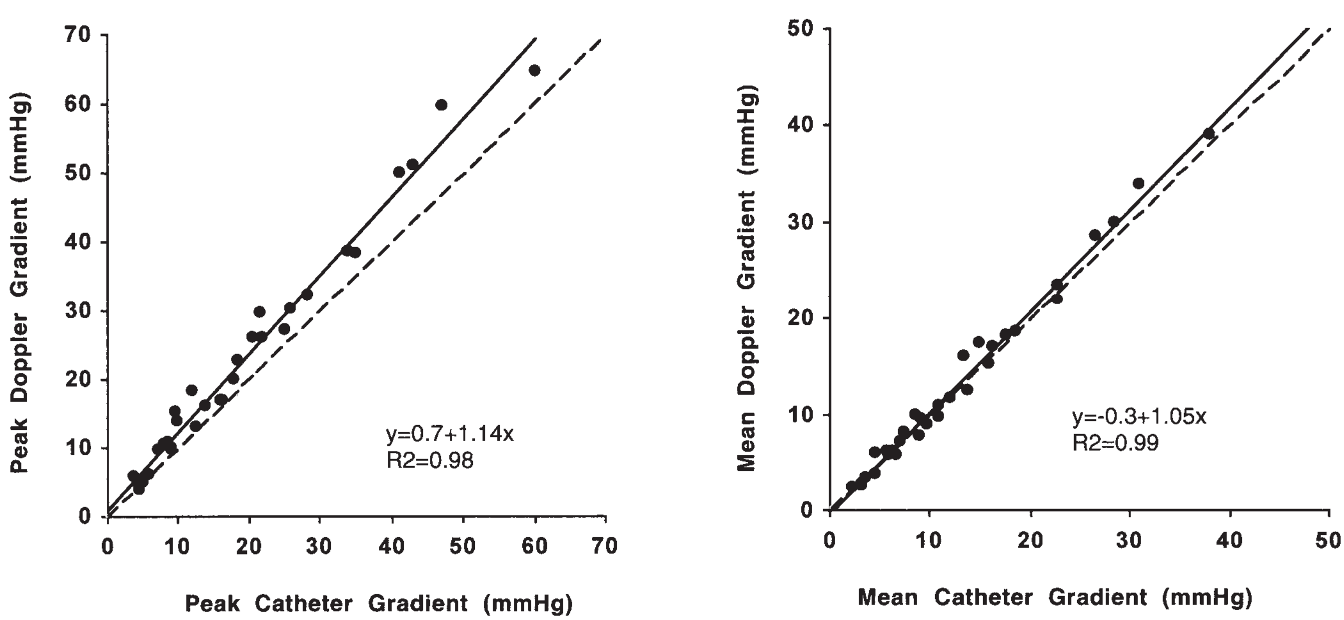
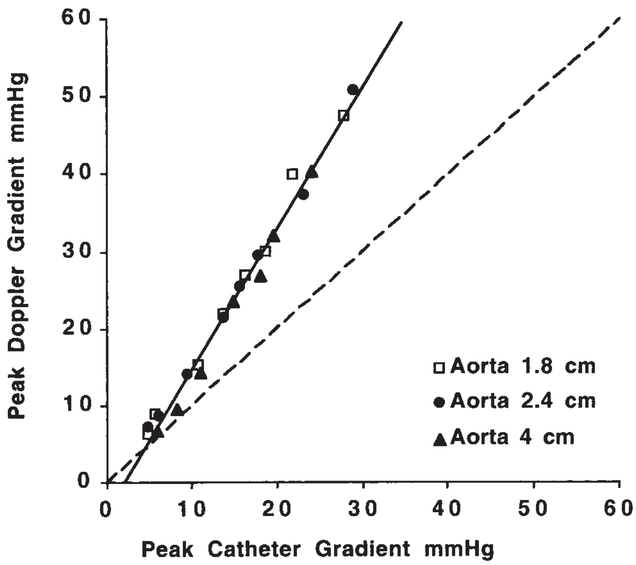


Figure 3: Peak and mean Doppler gradients versus peak and mean catheter gradients in Sorin tilting-disc prostheses.



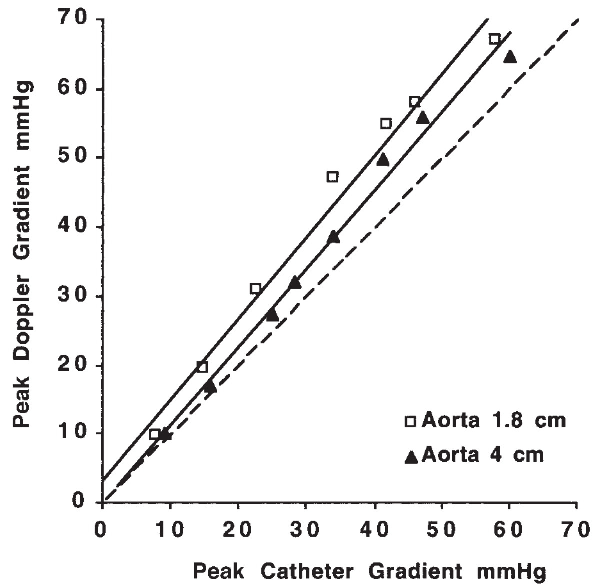


Figure 4: Effect of aortic size on the correlation between peak Doppler and peak catheter gradients shown for the 19 mm Edwards Mira bileaflet prosthesis with aortas 1.8, 2.4 and 4.0 cm in diameter (left), and for the 19 mm Sorin tilting-disc prosthesis with aortas 1.8 and 4.0 cm in diameter (right).

Edwards Mira 19 mm valve in set-ups with different aortic sizes. Similar results were obtained for all valve sizes in both On-X and Edwards Mira valves.

Sorin tilting-disc valve

In the Sorin tilting-disc valve, a significant pressure recovery was observed when the smallest aorta (1.8 cm diameter) was used. This resulted in an increased overestimation of catheter gradients by Doppler. With the 4 cm aorta, Doppler peak and mean gradients exceeded catheter peak and mean gradients by 13.4 ± 7.3% and 12.6 ± 14.1%, respectively. Using a 1.8 cm aorta, overestimation by Doppler increased to 28.6 ± 9.8% and 22.0 ± 10.3% for peak and mean gradients, respectively ($p < 0.05$; Fig. 4B). However, due to the small absolute differences between Doppler and catheter measurements in this type of prosthetic valve (Fig. 3), the increased overestimation caused by additional pressure recovery in the smallest aorta may not reach clinical relevance.

Discussion

Doppler-catheter gradient relationship

Discrepancies between Doppler and catheter gradients across bileaflet prosthetic aortic valves caused by localized high velocities and pressure recovery have been reported for several valve types (4-10). However, the Doppler-catheter gradient relationship for newly designed valves, such as On-X and Edwards Mira or Sorin Bicarbon bileaflet valves, has not been studied. Since newer valve types differ partially in their geometric design, these differences may also result in a different Doppler-catheter gradient relationship. Thus, previous reports for older valve types cannot automatically be applied to newer prosthetic valves. In-vitro

Table III: Sorin tilting-disc valves: Peak and mean gradients measured by Doppler and catheter techniques.

Valve size (mm)	Peak gradient				Mean gradient			
	Doppler (mmHg)	Catheter (mmHg)	Difference (mmHg)	Difference (%)	Doppler (mmHg)	Catheter (mmHg)	Difference (mmHg)	Difference (%)
19	37.4 ± 19.6	32.6 ± 16.6	4.8 ± 4.1	13.50 ± 7.3	22.1 ± 11.4	20.8 ± 11.2	1.3 ± 0.9	10.0 ± 11.0
21	25.1 ± 15.1	21.5 ± 19.9	3.6 ± 2.4	15.8 ± 7.8	14.5 ± 8.8	14.6 ± 8.5	0.4 ± 0.6	3.8 ± 6.1
23	15.7 ± 9.1	13.6 ± 6.6	2.1 ± 2.9	10.6 ± 13.9	9.4 ± 5.4	9.3 ± 4.2	0.4 ± 1.5	3.1 ± 15.6
25	11.1 ± 4.8	7.9 ± 2.7	3.1 ± 2.2	35.8 ± 22.6	6.8 ± 2.9	6.6 ± 2.8	0.2 ± 0.3	3.1 ± 5.0

studies such as the present investigation appear, therefore, indispensable to provide the essential information that allows adequate interpretation of Doppler data. The fact that Doppler echocardiography has become the first-line diagnostic tool for the assessment of heart valve prostheses underlines the need for this type of investigation.

Correlation between Doppler and catheter gradients was excellent in the valves evaluated in the present study. Nevertheless, Doppler significantly and consistently overestimated catheter gradients (Fig. 2; Tables I and II). In comparison with previous reports on bileaflet aortic prostheses, the relationship between Doppler and catheter gradients remained roughly unchanged (4,6,9). Slopes of the regression lines varied from 1.59 at peak for the Edwards Mira valve to 1.8 at peak for On-X valve gradients (Fig. 2). For peak gradients in St. Jude Medical valves, a slope of 1.76 has been reported (6), while in CarboMedics and Duromedics bileaflet valves the slopes varied from 1.95 to 2.09 (9). Discrepancies between Doppler and catheter gradients, therefore, appear to be common to all bileaflet aortic valve prostheses, regardless of their specific design.

In contrast to bileaflet aortic valve prostheses, data on the Doppler-catheter gradient relationship in tilting-disc valves are still limited, and the results are variable. Some investigators (6,11) have demonstrated an acceptable agreement between Doppler and catheter techniques (Medtronic Hall and Björk-Shiley valves), while others (8,10) found significant discrepancies (Omnicarbon and Björk-Shiley valves). In the present study, the Sorin Allcarbon tilting-disc valve was also assessed. Although the pressure drop across this prosthesis was higher than across both bileaflet valves (14,20-24), excellent correlation and acceptable agreement between peak and mean Doppler and the corresponding catheter gradients were observed (Fig. 3; Table III).

Thus, tilting-disc valves may require individual consideration, but an absence of clinically relevant discrepancies between Doppler and catheter measurements can mostly be expected.

Influence of aortic size on Doppler-catheter gradient relationships

It has been shown previously that pressure recovery can cause significant differences between Doppler and catheter gradients in aortic stenosis (17,18). The size of the ascending aorta has been found to be the most important variable for the occurrence of clinically relevant pressure recovery, which can be expected when the diameter of the aorta is smaller than 3 cm (18). However, whether this also applies to prosthetic aortic valves has not been sufficiently evaluated.

Based on the results of the present study, it appears that aorta size does not significantly influence the Doppler-catheter gradient relationship in On-X and Edwards Mira bileaflet valves (Fig. 4A). As shown by the present authors (4) and by others (5), pressure recovery in bileaflet valves occurs predominantly between the leaflets, though some additional pressure recovery can be found further downstream from the valve (4,5). Only this second phase of pressure recovery has indeed been shown to depend on the size of the receiving chamber (5). Vandervoort et al. (5) were unable to measure any distal pressure recovery in an experimental set-up with a large distal chamber, whereas a small but variable amount of pressure recovery was detected when a small distal chamber was used. However, total pressure recovery changed only slightly, by <10%. These small changes may not be recognized when large differences between Doppler and catheter measurements due to localized gradients and pressure recovery between the leaflets - phenomena which are independent of aortic size - are present.

The situation is different in tilting-disc valves, however. No pressure recovery is present at the level of the valve; thus, depending on the size of the receiving chamber, only downstream pressure recovery may occur. Indeed, in the present study changing differences were observed between Doppler and catheter gradients depending on the size of the aorta in Sorin tilting-disc valves (Fig. 4B). However, in absolute terms these differences remained small and may not attain clinical relevance.

Study limitations

In-vitro models cannot precisely duplicate all complex flow dynamics that may be encountered in patients with aortic valve prostheses. The constant distance for the distal pressure measurement is a simplification. In theory, the distance required for maximal pressure recovery may be longer, and depend upon the orifice size and aortic diameter (24-26). However, the results of previous studies (4,6) have shown that most pressure recovery occurs within several centimeters beyond the obstruction. Differences between wall measurements at 50 mm and central measurements at 100 or 200 mm downstream from the stenosis are small, and clinically not relevant.

In conclusion, discrepancies between Doppler and catheter gradients, as reported previously for bileaflet aortic valve prostheses, can also be observed in newly designed bileaflet valves such as the Edwards Mira or Sorin Bicarbon and the On-X valve. Doppler gradients across Sorin Allcarbon tilting-disc valves, however, reflect catheter gradients with acceptable accuracy. Thus, discrepancies between Doppler and catheter gradients are common to all bileaflet valves, regardless of their specific geometric design, whereas tilting-disc valves may require individual consideration, but do not show such phenomena. The influence of aortic size on the Doppler-catheter gradient relationship in prosthetic valves appears clinically to be less relevant. The findings of the present study should be helpful in the correct interpretation of Doppler data when assessing the function of these heart valve prostheses in a non-invasive manner.

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