In vitro comparison of different mechanical prostheses suitable for replacement of the systemic atrioventricular valve in children

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Objective: The aim of the present study was to compare the hydrodynamics of 4 different mechanical prostheses fitting the atrioventricular annulus in children.

Methods: We tested different inverted aortic prostheses with a prosthesis–annulus relationship in the mitral chamber of the Sheffield pulse duplicator (Department of Medical Physics and Clinical Engineering, Royal Hallamshire Hospital, Sheffield, UK), analyzed by comparing the prosthetic housing diameter and the predicted annulus diameter based on body surface area (0.8 and 1 m^2 corresponding to an annulus diameter of 18.8–20.2 mm). The On-X 19 (On-X Life Technologies, Inc, Austin, Tex), SJM Regent 19 (St Jude Medical Inc, St Paul, Minn), Sorin Overline 18 (Sorin Biomedica, Saluggia, Italy), and Medtronic Advantage Supra 19 (Medtronic Inc, Minneapolis, Minn) valves with a housing diameter of 19 to 20 mm were hydrodynamically compared. The tests were carried out at increasing pulse rate of 72, 80, 100, and 120 beats/min for a stroke volume of 20 and 30 mL. Therefore, cardiac output ranged from 1.44 to 3.6 L/min.

Results: Regardless of the pulse rate and stroke volume, the Medtronic Advantage Supra valve showed the highest mean diastolic pressure difference at each cardiac output ($P < .05$). The mean gradients were significantly lower for the Sorin Overline valve regardless of the cardiac output, stroke volume, and pulse rate ($P < .05$). The effective orifice areas observed followed exactly the same behavior: the lowest for the Medtronic Advantage Supra valve and the highest for the Sorin Overline valve. The Sorin Overline valve showed the highest closure volumes ($P < .05$), and the On-X prosthesis showed the highest leakage volumes ($P < .05$). The Sorin Overline valve had the highest total regurgitant volume ($P < .05$), and the Medtronic Advantage Supra valve had the lowest total regurgitant volume ($P < .05$). The On-X valve showed the highest total energy loss regardless of the pulse rate at 20 mL of stroke volume, which was comparable to the SJM Regent and Sorin Overline valves at increased stroke volume. The Medtronic Advantage Supra valve showed the lowest total energy loss regardless of cardiac outputs ($P < .05$).

Conclusions: This hydrodynamic evaluation model allowed us to compare the efficiency of currently available valve prostheses suitable for atrioventricular replacement in children. Among these prostheses, the Sorin Overline valve showed the best diastolic performance. On the other hand, for total energy loss, the Medtronic Advantage Supra valve demonstrated excellent performance. (J Thorac Cardiovasc Surg 2012;143:558-68)

Repair of the mitral valve in children is the preferred surgical option, but dysplastic valves and complicated pathologies of the mitral apparatus may present technical difficulties, and valve replacement may be necessary.

Evaluation of the hydrodynamics of prosthetic valves is a useful indicator of expected clinical performance, but has the hypothetic differential hydraulic behavior between different prosthetic mitral heart valves been sufficiently and comprehensively revealed?

All valve substitutes are responsible for some residual stenosis because of the design, size, material, and implantation technique used. This can be minimized by an accurate surgical strategy and preoperative prosthesis selection.[1-5] To answer our question in this report, we analyzed the hydrodynamic performance of 4 bileaflet mechanical prostheses: On-X 19 (On-X Life Technologies, Inc, Austin, Tex), SJM Regent 19 (St Jude Medical Inc, St Paul, Minn), Sorin Overline 18 (Sorin Biomedica, Saluggia, Italy), and Medtronic Advantage Supra 19 (Medtronic Inc, Minneapolis, Minn). All prostheses, regardless of the manufacturer's nominal size, were fitted onto a 21-mm diameter valve holder of the Sheffield pulse duplicator (SPD; Department of Medical Physics

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Abbreviations and Acronyms

CO = cardiac output
EOA = effective orifice area
LA = left atrium
MVR = mitral valve replacement
PR = pulse rate
SD = standard deviation
SPD = Sheffield pulse duplicator
SV = stroke volume
TEL = total energy loss
TRV = total regurgitant volume
VCV = valve closing volume
VLV = valve leakage volume

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MATERIALS AND METHODS

The SPD is a system designed to perform pulsatile hydrodynamic testing of prosthetic heart valves by means of continuous measurement of flow and transvalvular pressure gradients (Figure 1). The system has been described in detail.[6-8] We tested different inverted aortic prostheses in the mitral chamber of the SPD with a prosthesis–annulus relationship analyzed by comparing the prosthetic housing diameter and the predicted annulus diameter based on the body surface area of the subjects. We considered a body surface area of 0.8 to 1 m^2 corresponding to an annulus diameter of 18.8 to 20.2 mm in children. Three production quality samples of each model were tested. Each valve was tested 10 times at each different cardiac output (CO). This resulted in 40 tests for each valve and 120 tests for each valve model. The mean and standard deviation (SD) of each measurement parameter for each test condition was calculated from the 10 repeated tests on each valve. The sizes of the tested valves fitting an annulus diameter from 18.8 to 20.2 mm were as follows: On-X, 19; SJM Regent, 19; Sorin Overline, 18; and Medtronic Advantage Supra, 19. We considered the housing diameter as external diameter, and a larger label size of each prosthesis could not be accommodated in a 21-mm SPD holder. The prostheses were hydrodynamically compared. Thus, the valves were inserted into the pulse duplicator holder composed of 2 O-rings, and the prosthesis was secured between these rings. A supplied rubber washer was used to fill and seal the gap between the 2 parts of the mounting ring. Therefore, paravalvular leakage was not allowed in any test. Simultaneous pressure measurements were recorded by using electromagnetic flowmeters and pressure transducers located upstream and downstream of the mitral valve. Each valve was tested at a different stroke volume (SV) and pulse rate (PR) to assess the change in the prostheses' hydrodynamics during hypothetic somatic growth. The tests were carried out at increasing PR of 72, 80, 100, and 120 beats/min for an SV of 20 and 30 mL. CO varied between 1.44 and 3.6 L/min (representative of 0.8–1.2 m^2 body surface area and in the range of COs required by the Food and Drug Administration for in vitro tests). The aortic pressures were kept constant at 120/80 mm Hg. The system was filled with saline solution (0.9%), as recommended by the manufacturer, to optimize measurements.[9] Forward flow pressure decrease, closing volume, leakage volume, total regurgitant volume (TRV), and effective orifice area (EOA = [root mean square diastolic flow rate {milliliters/second}/51.6 * square root mean diastolic pressure difference {millimeters mercury}/1.0085]) were calculated as previously published by Walker and colleagues[10] and according to the SPD Manual (Figure 2). All data were expressed as means ± SD. The chi-square test was used for statistical comparison. The following parameters were determined for each cardiac cycle: mean gradient (millimeters mercury), EOA (square centimeters), performance index (EOA, square centimeters/external diameter, centimeters), TRV (milliliters), valve closing volume (VCV, milliliters), valve leakage volume (VLV, milliliters), and total energy loss (TEL, calculated by integrating the flow times the transvalvular pressure over relevant flow interval). A conversion factor of 0.1333 is applied to convert the energy from millimeters mercury to millijoule). All 7 mitral timing points considered by the SPD software are shown in Figure 2.

RESULTS

Measurements for All Valve Models (Figure 3)

Table 1 shows the measurements for all valve models by nominal size. The value is a mean measurement made with a highly professional ruler. Two different independent investigators measured all the prostheses. Measurements are the expression of a mean value of 3 different valves for each model, including the maximum and minimum values obtained for each valve.

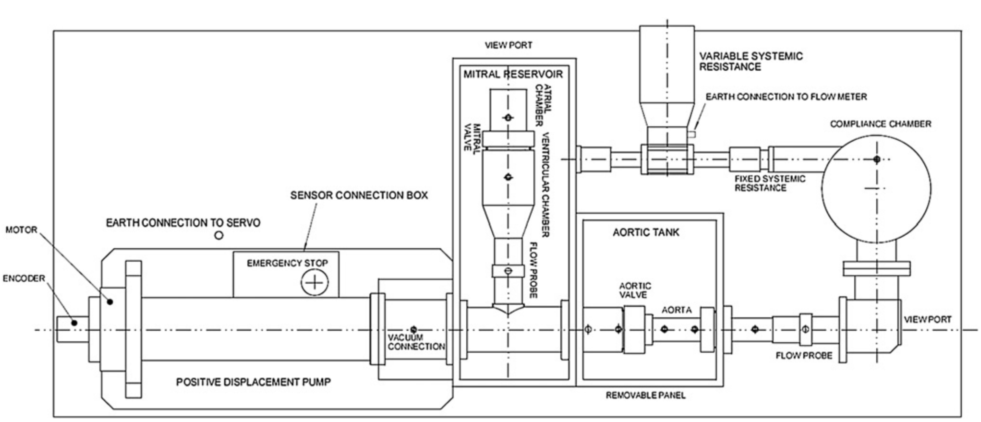

FIGURE 1. The SPD. (Reprinted with permission from the SPD Instructions Manual, page 5.[9])