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Long and Short Term Evaluation of Freestyle Stentless Bioprosthesis by Cardiovascular Magnetic Resonance (CMR)

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Abstract: Background: The aortic valve disease is a condition where main function of the valve which allowing the blood to pass from the main pump of the heart (left ventricle) into the main vessel of the body (aorta) in one direction is compromised either by stenosis or regurgitation. This condition is usually managed surgically by valve replacement with either biological tissue valve or metallic valve. **Objective:** Stentless xenograft bio-prosthesis may be the future valve of choice for aortic valve replacement. And since few studies have investigated the Medtronic Freestyle Stentless bio-prosthesis® (Medtronic Inc., Minneapolis, MN, USA) as a full root replacement, the study aim was to evaluate the long and short-term clinical outcome after aortic valve replacement with the Medtronic Freestyle bio-prosthesis (Medtronic Inc, Minneapolis, MN, USA), regarding distensibility and pulse wave velocity (PWV). **Material and Methods:** The study will include 50 patients who underwent aortic valve replacement using the Medtronic Freestyle Stentless bio-prosthesis® (Medtronic Inc., Minneapolis, MN, USA) and presented for evaluation by cardiovascular magnetic resonance (CMR) following the procedure at 1 year and 3 years intervals to evaluate aortic root stiffness by aortic distensibility, and pulse wave velocity (PWV). This will be a good indicator about the life span of this bio-prosthesis. The study was performed after approval of the Ethical committee of scientific Research, faculty of medicine, Ain Shams University. **Results:** The study suggests that the changes that happened regarding the pulse wave velocity (PWV) and distensibility during the 1 year and 3 years follow up was detectable. We compared the measures of the pulse wave velocity (PWV) and distensibility to the mean Pulse wave velocity (PWV) and distensibility of the normal population. The pulse wave velocity (PWV) increased in both measures while the distensibility decreased, suggesting an increase in the stiffness co-efficient of the Free-style aortic root. **Conclusion:** The use of Freestyle stentless bio-prosthesis seems as a good option for management of aortic valve diseases as well as aortic root diseases in elderly patients as It has a superb hemodynamics compared to mechanical prosthesis without the need for the long term use of anti-coagulants.

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1. Introduction

The Freestyle stentless (Medtronic Inc, Minneapolis, Minn) aortic bio-prosthesis is a xenograft composed of a thin synthetic sewing cuff attached to a glutaraldehyde preserved porcine aortic root using an alpha-amino oleic acid leaflet as an anti-calcification treatment. Unlike other bio-prosthesis, the Freestyle aortic bio-prosthesis does not have a stent and the absence of stent has been reported to provide better hemodynamic properties compared with stented biological valves, with less turbulent flow and larger efficient effective orifice area [(1)].

The Freestyle aortic root is inserted surgically by transecting the aorta just above the sino-tubular ridge and mobilizing the coronary ostia in order to have access to and remove the diseased aortic valve and insert the proximal end of the Freestyle aortic root in its place, while the distal end is sewn end to end with the ascending aorta [(2)].

The quality of images and therefore the diagnostic capability of a cardiovascular magnetic resonance (CMR) study in a patient with PHV depend on artefacts from the metallic components of the PHV since this valve is stentless with no metallic component, the quality and diagnostic capabilities of cardiovascular magnetic resonance (CMR) is very high.

Aortic stiffness is increasingly used as an independent predictor of adverse cardiovascular outcomes. So, evaluation of the impact the Freestyle stentless (Medtronic Inc, Minneapolis, Minn) aortic bio-prosthesis upon aortic vascular function using cardiovascular magnetic resonance (CMR) measurements of aortic distensibility and pulse wave velocity (PWV) will be very informative. [3]

Aim of the Work

Stentless xenograft bio-prosthesis may be the future valve of choice for aortic valve replacement. And since few studies have investigated the Medtronic Freestyle Stentless bio-prosthesis® (Medtronic Inc., Minneapolis, MN, USA) as a full root replacement, the study aim was to evaluate the long and short-term clinical outcome after aortic valve replacement with the Medtronic Freestyle bio-prosthesis (Medtronic Inc, Minneapolis, MN, USA), regarding distensibility and pulse wave velocity (PWV).

2. Material and Methods

The study will include 50 patients who underwent aortic valve replacement using the Medtronic Freestyle Stentless bio-prosthesis® (Medtronic Inc., Minneapolis, MN, USA) and presented for evaluation by cardiovascular magnetic resonance (CMR) following the procedure at 1 year and 3 years intervals to evaluate aortic root stiffness by aortic distensibility, and pulse wave velocity (PWV). This will be a good indicator about the life span of this bio-prosthesis.

The study was performed after approval of the Ethical committee of scientific Research, faculty of medicine, Ain Shams University.

Inclusion Criteria:

Patients with Freestyle stentless bio-prothesis. Above 18 years old.

Exclusion Criteria:

Patients known to have contraindications for MRI, e.g. an implanted magnetic device, pacemakers or claustrophobia. Patients with bad general condition needing life support and those with severe hepato-renal disease.

Cardiac magnetic resonance imaging (CMR)

Preparation before procedure:

Explanation of the procedure to the patient especially the side effects of the contrast agent including; coldness, warmth, or pain at the site of injection, nausea, vomiting, headache, paresthesia, dizziness and itching. They should be aware of the severe life-threatening anaphylactoid or nonallergic anaphylactic and nephropathic effect. Exclusion of any hazards like functioning MRI-incompatible pacemaker. Review kidney function test to avoid nephrogenic systemic fibrosis which may happen in case of contrast administration with acute or chronic renal failure (contrast shouldn't be given in estimated glomerular filtration rate <30 ml/min/1.73 m2).

During procedure:

Physiological monitoring devices and hearing protection are put in place. A high-quality electrocardiogram (ECG) signal is essential for optimum data quality in cardiac-gated sequences. The imaging coil should be chosen to maximize the signal-to-noise ratio over the body region to be examined. MR compatible equipment should be used to monitor the heart rate, transcutaneous oxygen saturation, blood pressure, expired carbon dioxide and body temperature. An appropriately equipped resuscitation cart and emergency management plan for the MR environment should be in place. Specialized anesthesia team attends all procedures with anesthesia.

Technique of imaging:

Machine used is 1.5 T scanner ***(Siemens Magnetom Aera, Siemens Medical Systems, Erlangen, Germany).*** White blood images which help in assessment of the cardiac output of both left ventricles. Injection of gadolinium-based contrast agent (**Magnevist, Schering AG, Berlin, Germany, 0.2 mmol/kg).**

After the procedure:

Examination is processed on a dedicated workstation **(Segment Medviso).**

Consent:

All patients or their relatives will be required to sign a written consent explaining the study. Any inquiries of the patient (s) will be explained thoroughly.

Statistics:

All the resulting data will be subjected to adequate statistical analysis, comparison, will be tabulated and then discussed.

Treatment in cases of risks and complications:

If allergy from contrast occurs (uncommon) it will be managed by using a plastic cannula for IV access & maintain IV access for 30 minutes with administration of antihistaminic and adrenaline. Immediate dialysis for patients with NSF Emergency

Phase contrast and flow assessment:

Aorta Q-flow phase contrast images which help in blood flow quantification in the aortic root. Measurements are performed with free breathing and multiple signal averages to prevent the effect of breath holding on the amount of blood passing in and out of the heart which confounds clinical interpretation. Scan parameters were: Repetition time (TR) 105.2 m/sec; echo time (TE) 2.97 m/sec; flip angle (FA) 20 degree; slice thickness 8 mm; matrix is 119x192, field-of-view is rotated to avoid wrap according the size of each patient and voxel size is modified according to the field of view. Images are acquired with retrospective ECG-gating, the reconstructed phases are 30 phases per R-R interval, velocity encoding starts from 150 cm/sec in aorta. The above mentioned MRI techniques are Faster and more robust magnetic facilitating the MRI-based PWV measurements. The

PWV is computed mathematically via the Moens-Korteweg equation.

MRI based PWV is measured clinically by measuring aortic mean velocity waveforms which is derived from a flow sensitive MR imaging sequence in the ascending and the descending aorta. This PWV is mainly affected by the temporal shift, Δt, in the flow waveforms as the vasculature is traversed. This temporal shift is inversely proportionate to the stiffness of the vessel, and the smaller the shift is, the greater the stiffness and the higher the PWV. [(4)]

The PWV is measured in all 50 patients at 1 and 3 years intervals post-operative and change is measured in percentage.

Aortic root distensibility:

Gradient echo phase-contrast cine MRI with ECG gating was performed to evaluate aortic distensibility, obtaining images of the ascending and descending in the transverse plane perpendicular to the aortic lumen at the level of the right pulmonary artery. Imaging parameters included repetition time: 10 m/s; echo time: 1.9 m/s; field of view: 34 cm; slice thickness: 8 mm; matrix: 256 × 224; temporal resolution: 20 m/s; encoding velocity: 150 cm/s; and bandwidth: 32 kHz. The aortic root distensibility is measured by the maximal (Amax) and minimal (Amin) aortic areas and change in aortic area defined as ΔA = (Amax-Amin) were used to calculate the distensibility of the ascending aorta (AAD) in each subject as follows, with PP being pulse pressure (in mmHg): AAD = ΔA/(Amin x PP) in 10^{-3} mmHg. The aortic root distensibility was measured with magnetic resonance imaging at baseline in the 50 participants at 1 and 3 years interval and the difference were measured in percentage.

3. Results

Table (1): Descriptive statistics

	n	**Min.**	**Max.**	**Mean**	**SD**
PWV.C	52	1.9	5.5	3.671	0.9093
PWV.1	52	2.34	10.62	5.3646	2.79016
PWV.2	52	4.38	11.2	6.7254	2.47418
PWV.dC_21	52	-0.101	1.275	0.37637	0.392783
PWV.dC_1C	52	-0.368	1.87	0.4499	0.754097
PWV.dC_2C	52	0.184	2.027	0.81767	0.668696
Distensibility. C	52	0.0017	0.0161	0.0089	0.003772
Distensibility.1	52	0.004	0.012	0.00678	0.002357
Distensibility.2	52	0.003	0.009	0.00573	0.001779
Distensibility.dC_21	52	-0.417	0.038	-0.13155	0.142772
Distensibility.dC_1C	52	-0.569	0.292	-0.23863	0.264803
Distensibility.dC_2C	52	-0.64	0.045	-0.35653	0.199916
Age	52	21	52	34.08	10.232

Table (2): Student t test

Females:					
	n	Min.	Max.	Mean	SD
PWV.C	16	1.9	5.5	3.7	1.1384
PWV.1	16	3.72	10.48	7.0925	2.91961
PWV.2	16	4.45	10.48	7.735	2.54486
PWV.dC_21	16	-0.101	0.694	0.16142	0.322412
PWV.dC_1C	16	0.005	1.832	0.91689	0.789084
PWV.dC_2C	16	0.203	1.832	1.09054	0.687799
Distensibility.C	16	0.0017	0.0161	0.0089	0.003718
Distensibility.1	16	0.004	0.012	0.00833	0.002714
Distensibility.2	16	0.004	0.009	0.00655	0.001541
Distensibility.dC_21	16	-0.417	0.024	-0.16752	0.174686
Distensibility.dC_1C	16	-0.528	0.292	-0.06461	0.304976
Distensibility.dC_2C	16	-0.517	-0.045	-0.26404	0.173194
Age	16	21	45	36	9.295

Males:					
	n	Min.	Max.	Mean	SD
PWV.C	36	1.9	5.5	3.658	0.8055
PWV.1	36	2.34	10.62	4.5967	2.39148
PWV.2	36	4.38	11.2	6.2767	2.33909
PWV.dC_21	36	0.014	1.275	0.4719	0.386974
PWV.dC_1C	36	-0.368	1.87	0.24234	0.646347
PWV.dC_2C	36	0.184	2.027	0.6964	0.632186
Distensibility.C	36	0.0017	0.0161	0.0089	0.003849
Distensibility.1	36	0.004	0.01	0.00609	0.001831
Distensibility.2	36	0.003	0.009	0.00536	0.001774
Distensibility.dC_21	36	-0.396	0.038	-0.11557	0.12558
Distensibility.dC_1C	36	-0.569	0.101	-0.31598	0.205709
Distensibility.dC_2C	36	-0.64	0.045	-0.39763	0.199333
Age	36	21	52	33.22	10.634

Table (3): Paired t test

	n	**Mean**	**SD**	**t**	**p**	**Sig.**
PWV.C	52	3.671	0.9093	-4.01	0	HS
PWV.1	52	5.3646	2.79016			
PWV.C	52	3.671	0.9093	-8.047	0	HS
PWV.2	52	6.7254	2.47418			
PWV.1	52	5.3646	2.79016	-7.493	0	HS
PWV.2	52	6.7254	2.47418			
Distensibility.C	52	0.0089	0.003772	3.176	0.003	HS
Distensibility.1	52	0.00678	0.002357			
Distensibility.C	52	0.0089	0.003772	5.124	0	HS
Distensibility.2	52	0.00573	0.001779			
Distensibility.1	52	0.00678	0.002357	5.785	0	HS
Distensibility.2	52	0.00573	0.001779			

Table (4): Pearson Correlation Test

	PWV.C			**PWV.1**			**PWV.2**		
	r	p	Sig.	r	p	Sig.	r	p	Sig.
Age	-0.011	0.938	NS	0.296	0.033	S	0.313	0.024	S
PWV.C				-0.13	0.357	NS	-0.121	0.395	NS
PWV.1							0.883	0	HS

Table (5): Pearson Correlation Test.

	Distensibility. C			**Distensibility.1**			**Distensibility.2**		
	r	p	Sig.	r	p	Sig.	r	p	Sig.
Age	-0.007	0.959	NS	0.11	0.436	NS	-0.009	0.951	NS
Distensibility.C				-0.195	0.165	NS	-0.189	0.179	NS
Distensibility.1							0.836	0	HS

4. Discussion

The Freestyle stentless bio-prosthesis was introduced to offer a better option with superior hemodynamics to other xenografts as well as well as eliminating the issues associated with mechanical prosthesis and since the use of the bio-prothesis are usually reserved for elderly patients due to the structural changes associated, this study analyzed the data with respect to the age and gender of the patients.

The study suggests that the changes that happened regarding the pulse wave velocity (PWV) and distensibility during the 1 year and 3 years follow up was detectable. We compared the measures of the pulse wave velocity (PWV) and distensibility to the mean Pulse wave velocity (PWV) and distensibility of the normal population. The pulse wave velocity (PWV) increased in both measures while the distensibility decreased, suggesting an increase in the stiffness co-efficient of the Free-style aortic root.

Using paired t test, the changes in the pulse wave velocity (PWV) and the distensibility in the 1 year follow-up and the 3 years follow-up when compared to the pulse wave velocity of the control group were highly significant as the probability of error was zero.

The mean age which was 34.08 was correlated to the results using Pearson correlation test, which showed there is a significant change regarding the age as their probability of error was below 0.05, suggesting that the prevalence of structural changes of the of the Freestyle aortic root will increase with age.

The study compromised of 36 men and 16 women, so sex as well was correlated to the results using the Student t test, showing that men are more subjected to structural changes during the 1 year follow up a the results came out highly significant while it started to decrease in the 3 years follow up as the results decreased to just significant, suggesting that men are more prone to structural changes during the short term post-operative while the probability starts to decrease becoming almost the same during the long term follow-up post-operative.

Moreover, when comparing the pulse wave velocity (PWV) control and the distensibility control to the changes between the control and 1 and 3 years follow up using Pearson correlation test, the results came out non-significant suggesting that the hemodynamics are preserved in all 52 candidates regardless of their age and sex.

The Freestyle stentless bio-prosthesis will undergo structural changes that will affect the stiffness coefficient of the prosthesis, and these changes will be more prominent with older patients. Moreover, men are more prone to these changes during the immediate post-operative period yet becoming almost the same as females over time which was shown in the long term follow-up. Yet, since the hemodynamics are not affected over the short and long term follow-up, the Freestyle stentless bio-prosthesis seemed as a good option for all the groups.

Conclusion

The use of Freestyle stentless bio-prosthesis seems as a good option for management of aortic valve diseases as well as aortic root diseases in elderly patients as It has a superb hemodynamics compared to mechanical prosthesis without the need for the long term use of anti-coagulants.

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