

First experience of tri-leaflet heart valve prostheses TRICARDICS in patients with mitral heart disease

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Results shown on heart valves replacement with mechanical artificial tricuspid valves Tricardics manufactured by OOO Roscardioinvest. Analysis of direct results in 9 patients carried out. The patients underwent mitral valve replacement. During 3-6 months period under medical observation there were no replacement-due complications detected. This allows to conclude that replacement procedures using Tricardics have proved to be effective.

Key words: mitral heart disease, artificial tricuspid valve, valve replacement, Tricardics, mitral valve, hemodynamics findings, pressure gradient.

Heart valve prosthesis is well-known and developing part of cardio surgery and cardiology both in connection with fast hi-tech progress and with existing problems with heart valve prostheses nowadays, such as thrombosis and infection. An ideal prosthesis must imitate hemodynamics functions of natural valve. Tissue valves follow these requirements more than mechanical valves, because they have good hemodynamics parameters and high thrombus resistance (Fig. 1). Despite this tissue valves in 45% of cases become disable in first 10 years after implantation. As a result they are not implanted to young patients. Mechanical valves are quite durable but they can cause thrombus, infection, hemolysis and change of hemodynamic parameters, especially in long-term period.

Also there are problems with the shape and size of mechanical prostheses. It was proven that the smaller the effective area of aortic prosthesis the higher the insufficiency of left ventricle probability is (first diastolic and after systolic). This is pressing problem in choosing the size of prosthesis implanted in aortic position.

Nowadays are widely used bi-leaflet mechanical heart valves which have not high valve gradients, high thromboresistance and long-term survival of patients after operation.

Further development of mechanical heart valves is tri-leaflet valves. New tri-leaflet prosthesis was named 'TRICARDICS' (Fig. 2).

The creation of tri-leaflet heart valve will allow not only making the same shape as natural valve, but also physiological conditions of blood flow through the valve.

Tri-leaflet heart valve 'TRICARDICS' is titanium ring with three leaflets fixed in it with hinges. With fully opening of the valve on angle $\approx 88^\circ$ axial blood flow through the valve is provided, at the same time there are no elements disturbing the blood flow, and therefore no energy loss. These features make this valve differ from all existing mechanical valves.

The titanium housing provides reliability and durability of the valve, and helps to get the smallest thickness of the housing. This allows making the effective area bigger.

Ion implantation of carbon into titanium ring surface is made to provide biocompatibility and thromboresistance.

The leaflets of the valve are made of standard material, used in Russia for closing elements of the valves, - uglesital, alloyed with boron.

The shape of the leaflet is brand new and does not disturb the blood flow. Hydrodynamic tests shown that the closing time is 2 times less than in St. Jude valve

and is almost the same as in natural valve (The Institute of mechanical problems RAS, Dr. Yurechko).

Reliability and quality of the valve is guaranteed not only with design and materials, but also with technology. Manufacture technology allows moving regurgitation zones in the hinges area.

Using "TRICARDICS" is possible in the following cases:

1. Pathology of mitral valve:
 - a) rheumatic lesions,
 - b) congenital pathology of valve tissue (myxomatosis),
 - c) infectious lesions of the valve.
2. Pathology of aortic valve:
 - a) rheumatic lesions,
 - b) congenital pathology of valve tissue (myxomatosis, bi-leaflet valve),
 - c) infectious lesions of the valve,
 - d) calcinosis of leaflets.
3. Pathology of tricuspid valve:
 - a) contra-indication for tissue valve implantation in this position,
 - b) congenital heart disease when this valve is systemic.

This research is dedicated to first experience of tri-leaflet heart valve prosthesis TRICARDICS in patients with mitral heart disease.

Data and methods

In period from June till October 2007 in Bakulev's research center 9 prostheses were implanted in mitral position. 3 men and 6 women were operated; average age was 49.8 ± 7.6 years old. In six cases the cause of mitral heart disease was rheumatism and in three cases – myxomatous degeneration (Fig. 3, 4).

Standard protocol of operation included excision of pathologically changed mitral valve and implantation of new prosthesis TRICARDICS. Operation was made using cardiopulmonary bypass and cardioplegia. In 4 cases operation was added by "Labyrinth" procedure made by r-

method, plastic of tricuspid valve by Boyd – 3 cases, on ring Carpentier – 2 patients.

#27, 29 and 31 prostheses were used. In early follow-up the amount of general and valve-dependent complications was estimated, hemodynamic data of prostheses, 3D reconstruction of prostheses was made.

Results

According after surgery echocardiogram pick gradient in valves was from 8 to 15 mmHg, av. diastolic gradient – from 3 to 8 mmHg, blood flow on colored Doppler research has 4 flows of regurgitation of small streams in area of sides of prosthesis, length not more than 7 mm (Fig. 5, 6).

During 3D reconstruction images research of both auricle and ventricle areas of TRICARDICS prostheses implanted in mitral position all three disks are observed as clear signals at the level of 12, 15 and 19 hours with good amplitude of motion. The picture from ventricle surface is more informative (Fig. 7, 8).

There were no valve-related complications in early follow-up. All patients got standard anticoagulation therapy by low-molecular heparins in combination with non-direct anticoagulants (warfarin and syncumar) with following selection of dose for supporting IRN 3.0-3.5.

In post-operative period 2 patients had impaired cardiac function, 3 had rhythm disturbance, namely relapse of auricle fibrillation. In first case patient was full of cordarone and sinus rhythm was restored medicamentously. In two other cases electro impulse therapy was necessary, in one patient repeatedly.

Below you will find clinical case 1.

Patient B., 44 years old, diagnosis "the syndrome of tissue dysplasia". Mitral valve prolapse with total insufficiency. Relative insufficiency of tricuspid valve II degree. Constant form of auricle fibrillation, tachysystolic form. Insufficiency of blood circulation IIa degree."

Despite standard pre-operation research, transesophageal ECHO and

transthoracic ECHO with 3D-reconstruction were made to clarify the diagnosis (Fig. 9).

The following operation was made: implantation of mitral prosthesis TRICARDICS #31, Boyd plasty of tricuspid valve, modified procedure 'Labyrinth' made by r-method. Reduction of left auricle.

Post-operative period was without any complications.

After 6 months follow-up patient has sinus rhythm, ECHO shows full motion of the prosthesis, regurgitation with 4 flows, length no more than 7-8 vv (Fig. 10, 11).

Discussion

As known mechanical prostheses of heart valves had a long history and evaluated from cage-ball, disc, single- and bi-leaflet valves to tri-leaflet valves. Improvement of design and technical characteristics of prosthesis was done to reduce risk of thrombosis. Upgraded tri-leaflet valves "Triflo" were the best on pre-clinical stage. This prosthesis was in vivo tested by R. Gallegos et. all in 2006. The aim of pre-clinical research was to estimate the characteristics of prostheses "Triflo" and to define the possibilities to use them effectively in human.

Tri-leaflet heart valve, which is like normal aortic heart valve was used for our research, as for R. Gallegos et. all research. Regurgitation through prosthesis has 4

flows. In our research the length of the back flow in left auricle was no more than 7 mm. the design of the valve was made the way to reduce the risk of thrombosis. Even without anticoagulation. In the research of R. Gallegos et. all sheep with implanted tri-leaflet valves did not get anticoagulants. The period of observation in two groups was 150 and 365 days respectively. The results for both groups were compared. The risk of thrombosis in both groups was from 4 to 20 %, with the same frequency of thrombosis in mitral and aortic prostheses. In one case the sheep with aortic prosthesis has embolism in renal artery followed by renal infarct, and in one case – dysfunction of the leaflet of the prosthesis because of the coat in hinge area, which disturbed the closing function of the prosthesis.

In our research the period of investigation was 3 to 6 months. During that period there were no valve related complications, however patients followed the prescribed regime of anticoagulant therapy (IRN maintains from 3.0 to 3.5).

Conclusion

First experience of tri-leaflet heart valve "TRICARDICS" prostheses allows saying about their successful work. For their durability and reliability confirmation further research needed.

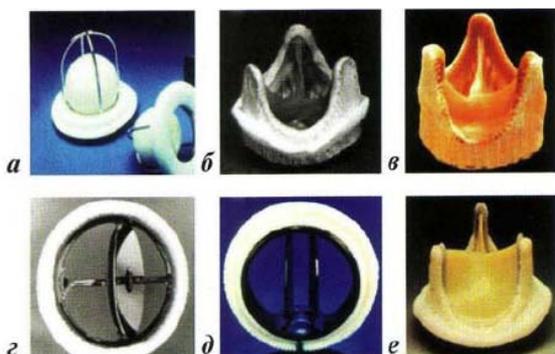


Fig. 1. The evolution of heart valve prostheses – from cage ball and disk (a, z) to bi-leaflet (d) and tissue (b, v, e).



Fig. 2. Tri-leaflet heart valve prosthesis "TRICARDICS".



Fig. 9. 3D-Echo – picture (the same patient). Myxomatosis of the valve. Back mitral valve is more than front, the chink is between them (partial co-optation).



Fig. 10. 2D-Echo – picture (the same patient). Mitral position of “TRICARDICS” – the leaflets are shown.



Fig. 11. 2D-picture in colored flow through the prosthesis “TRICARDICS” in mitral position (the same patient).