

RESULTS OF TAVI WITH THE USE OF A VALVE WITH PTFE LEAFLETS

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BACKGROUND

TAVI is a topic of great interest to cardio-thoracic surgeons of the world today. There are valves that have undergone trials, with good immediate and long-term results. All biological prostheses contain cusps made of biological material. 4 years ago, started clinical trial of a new valve for TAVI, the cusps of which contain PTFE.

OBJECTIVE

To evaluate the clinical and hemodynamic results of transcatheter replacement of the aortic valve with the “MedLab-KT” prosthesis.

METHODS

MedLab-KT is the first model of a transcatheter prosthetic with PTFE leaflets. It is a balloon-expandable stent, the cusps of which are made of 0.1 mm thick polytetrafluoroethylene plates. The reason of choice of synthetic material was the hypothesis of the absence of biodegradation of polytetrafluoroethylene in the organism. The valve has passed the preclinical phases of the in vitro and in vivo tests.

The study included 100 patients who had undergone implantation of the MedLab-CT prosthesis. Evaluated the in-hospital frequency of deaths, myocardial infarction, stroke, large bleeding, renal insufficiency, permanent pacemaker implantation and the gradient on the valve, by ultrasound. In the mid-term survival rate and the frequency of a clinically significant stroke, as well as hemodynamic parameters according to echocardiography for up to 4 years, were evaluated.

RESULTS

The majority of patients belonged to the elderly group (mean age 73.3 years). For 54 patients (54%) according to the STS scale, a high risk of surgical intervention was determined: $\geq 8\%$. We had 5(5%) deaths and 1 case of stroke in the early period. The average follow-up was 11.6 months, the maximum - 4 years. Mortality was 9%, 5 deaths were noted at the hospital stage, 4 patients died in the long-term period. In the internal examination group, the average gradient on the aortic valve prosthesis is defined at 8.41 ± 4.21 mm Hg; failure due to paraprosthetic fistulas not higher than I degree was noted in 7 patients (7%), not higher than II degree in 1 case; transvalvular aortic insufficiency was not detected.

CONCLUSION

The results of the studied parameters are comparable with the data provided by foreign randomized clinical studies of famous models of transcatheter aortic valve prostheses.