DOI: 10.23934/2223-9022-2019-8-1-87-92

Perceval S Sutureless Prosthesis in Aortic Valve Replacement

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BACKGROUND In 12–47% of patients, there is a need to repeat the aortic valve replacement due to various valve-related complications in the immediate and late postoperative period. The standard operation of repeated aortic valve replacement is a complex procedure and it is associated with an increased risk due to adhesions in the pericardial cavity, previously performed coronary bybass surgery, difficulties of excision of the previously implanted prosthesis, narrow fibrous aortic valve ring and aorta. In 2007, the sutureless Perceval S aortic valve bioprosthesis (Sorin Group, Italy) was introduced into clinical practice. One of the advantages of such a prosthesis is the convenience of its anatomical positioning during repeated operations and the absence of the need to fix the prosthesis with sutures.
The aim of study was to summarize the experience of sutureless implantation of the aortic valve prosthesis during repeated replacement.
MATERIAL AND METHODS We report the results of treatment in 3 patients with valve-associated complications, who underwent aortic valve repeated replacement with the Perceval S sutureless prosthesis.
RESULTS There were no hospital mortality and paraprosthetic regurgitation in the repeated replacement of the aortic valve with the Perceval S sutureless prosthesis. Two patients required implantation of a permanent pacemaker due to the development of a complete atrioventricular block, which was not related to the model of the prosthesis used.
CONCLUSION The use of aortic valve prosthesis in cardiac surgery, which does not require fixation with sutures, allows non-standard decisions to be made in the surgical treatment of patients with various complications of previously performed aortic valve replacement and provides good immediate results if repeated replacement is necessary.
Keywords: aortic valve, rereated replacement, surgical treatment, sutureless fixation of the prosthesis, artificial blood circulation
For citation Sokolov V.V., Kovalyov A.I., Vladimirov V.V., et al. Perceval S sutureless prosthesis in aortic valve replacement. Russian Sklifosovsky Journal of Emergency Medical Care. 2019; 8(1): 87–92. DOI: 10.23934/2223-9022-2019-8-1-87-92 (In Russian)
Conflict of interest Authors declare lack of the conflicts of interests
Acknowledgments The study had no sponsorship
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AC — artificial circulation
AV — aortic valve
CABG — coronary artery bypass grafting
CVP — central venous pressure
EchoCG — echocardiography
EDV — end diastole volume
EF — ejection fraction
FR — fibrous ring
IVS — interventricular septum
LV — left ventricle
PA — pulmonary artery
RCA — right coronary artery
RV — right ventricle

INTRODUCTION

The experience of aortic valve replacement (AV) has more than half a century of history. Today, AV pathology, which requires surgical therapy is second in the frequency of occurrence after coronary artery disease [1, 2]. The “golden standard” is still an open surgery when AV prosthetics is fixed to the fibrous ring (FR) of the AV after excision of the latter under conditions of artificial blood circulation (AC). In 12–47% of patients, due to various valve-related complications of the immediate and late postoperative periods, there is a need for AV repeated replacement [3-5]. In

Russia, in 2016, 6,071 AV replacements were performed, including 270 AV repeated replacements, which accounted for 4.4% of the total number of interventions on AV [1]. According to various authors, the number of patients who need to replace the AV is constantly growing [6–8].

Any repeated heart surgery compared with primary interventions is associated with a high risk of various complications and an increase in the number of deaths, which is associated with technical difficulties in performing such an operation due to adhesions. With repeated operations to replace AV, hospital mortality, according to the literature, varies from 2.3 to 17.6% [9–11]. In our country, mortality in the repeated replacement of various heart valves is 8.9% [1]. The main predictors of adverse results in repeated operations are the longer duration of AC and myocardial ischemia, as well as structural changes of FR [12].

In 2007, the Perceval S heart bioprosthesis (Sorin Group, Italy), designed for sutureless implantation came to the clinical practice [13–15]. One of the advantage is the convenience of its anatomical positioning during repeated operations [16]. The use of the Perceval S prosthesis with repeated interventions is only being introduced into clinical practice, so few observations are of interest.

The purpose of this work is to summarize the experience of using the technique of sutureless implantation of an AV prosthesis during repeated replacement.

CLINICAL OBSERVATIONS

The first implantation of the Perceval S prosthesis was performed at the Emergency Department of Cardiac Surgery, Cardiopulmonary Bypass and Heart Transplantation of the N.V. Sklifosovsky Research Institute for Emergency Medicine in December 2013. Routinely, this method began to be used in April 2017. In October 2018, 26 sutureless implantations of Perseval S prosthesis with AV stenosis were performed, including 3 cases with AV reprosthesis due to valve-related complications.

Clinical observation 1

Patient Z., 75 years old, was admitted in April 2017 with complaints of dyspnea with minimal exertion and a decrease in exercise tolerance. The combined AV defect with a predominance of stenosis was verified. According to echocardiography (EchoCG), AV is tricuspid, the leaflets are thickened, calcium deposits in leaflets and FR, the aortic root diameter is 3.0 cm, the peak gradient on AV is 75 mmHg., average - 43 mm Hg., regurgitation in the left ventricle (LV) grade 1, end-diastolic volume (EDV) LV 100 ml, LV ejection fraction 64%, interventricular septum thickness (IVS) 1.2 cm, thickness of the posterior wall of LV 1.2 cm, systolic pressure in the pulmonary artery (PA) 38 mm Hg. No pathology was detected during coronary angiography. The EuroSCORE II index was 5.83%.

The replacement of AV with Braile Biomedica–21 prosthesis was performed.

From the operation protocol:

Median mini-sternotomy with access to the third intercostal space on the right. Aorta 2.5 cm in diameter. Bicuspid valve, rudimentary commissure between the coronary leaflets. Thickened leaflets, significant calcification of leaflets and FR, especially in the area of the right coronary sinus (calcification grade 3). The valve cuspids are excised. Decalcification of FR is performed. The FR of AV was sutured with U-shaped stitches, and bioprosthesis Braile Biomedica–21 was implanted in the subcoronary position. Aortic clamping duration 78 min.

Tracheal extubation was performed 4 hours after surgery. The patient was transferred from ICU the next day. The postoperative period was clinically uneventful.

When conducting a control EchoCG on the 3rd day, a discharge of blood from the aorta into the cavity of the right ventricle (RV) was detected in a small volume. On the 9th day after the operation, diagnostic aortography was performed , which confirmed the presence of regurgitation in the RV, increasing its degree grade 3. According to clinical data, patient was feeling relatively satisfactorily, there were signs of right heart failure: central venous pressure (CVP) to 170 mm Aq, liver enlargement, edema.

Given the presence of aortic-right ventricular fistula, the increasing effects of heart failure on the large circulation and the futility of conserv, repeated AV replacemet with the Perceval S-21 prosthesis and coronary artery bypass grafting (CABG) under AC conditions.

From the operation protocol:

Complete resternotomy. Dissected unchanged AV prosthesis. In the area of the right coronary sinus immediately above the FR, near the mouth of the low RCA, the sinus defect is detected with myocardial exposure and communication with the RV. It is not possible to detrmine the diameter of the defect due to the difficult access. Given the impossibility of plastics of the defect without involvement the RCA mouth, it was decided to bypass the RCA. The defect was sutured with three stitches Prolene 3/0 on Teflon gaskets, FR shifted in the left ventricle and there were doubts about the possibility of ensuring the subsequent reliable fixation of the AV prosthesis with sutures. At the same time, the rounded shape of the aortic root is preserved at the FR level. Under these conditions, the sutureless implantation of a bioprosthesis seemed to be appropriate. After the proper positioning, the bioprosthesis Perceval–21, which additionally covered the defect area with its cuff was implanted. After stitching of the aorta, CABG of RCA was performed. Myocardial ischemia lasted 152 minutes.

The postoperative period was uneventful, with the exception of the development of a complete transverse block (expected due to rougher manipulations on the FR!). Tracheal extubation was performed 6 hours after the surgery. The patients was transferred from the ICU 2 days later. On the 11th day, a permanent single-chamber pacemaker was implanted.

The control EchoCG: local myocardial contractility of the left ventricle is not disturbed, LV EF 55%. Peak gradient on the AV prosthesis 32 mm Hg, transprosthetic regurgitation grade 1, no paraprosthetic leaks.

The patient was discharged in satisfactory condition on day 17 after the second operation. According to EchoCG, in September 2018 (1 year 4 months after the second operation), the peak gradient on the prosthesis was 24 mm Hg, transprosthetic regurgitation grade 1, LV EF 63%.

Clinical observation 2

Patient Y., 56 years old, was admitted in June 2018 with complaints of dyspnea at rest and a decrease in exercise tolerance. In December 2008, the patient underwent AV replacement with the mechanical prosthesis MedEng-21 for infectious endocarditis. The patient periodically violated the reception of warfarin, the level of INR (International Normalized Ratio) was

not controlled. In May 2018, dyspnea appeared and began to grow.

The state of moderate severity upon admission. Swelling of the legs and feet. Breathing hard, accelerated to 23 per minute at rest.

According to EchoCG, the shadow of the mechanical prosthesis in the position of AV, the movement of the locking elements is limited, there are overlaps on the prosthesis, the diameter of the aortic root 3.5 cm, peak gradient on AV 106 mm Hg, medium 62 mmHg, regurgitation in the left ventricle grade 1–2, EDV 113 ml, LV EF 62%, IVS 1.1 cm, LV posterior wall thickness 1.2 cm, systolic pressure in PA 45 mm Hg. Coronarography was not performed. The EuroSCORE II index was 6.49%.

On the following day after the hospitalization, the patient under the following vital conditions underwent an operation: repeated perlacement of AV with the Perceval-21 bioprosthesis under AC conditions. The decision on the use of bioprosthesis in patients younger than 60 years was made in connection with the character of the arisen mechanical prosthetic dysfunction (thrombosis) and urging request of the patient to implant bioprosthesis in order to reduce the likelihood of thrombus formation on the new prosthesis in the future.

From the operation protocol:

In the AV position, the mechanical prosthesis MedEng–21. Locking elements are wedged by organized thrombotic masses in the open state. No paraprostetic fistulas. The AV prosthesis is excised. At the same time, dissection of FR tissue in the area of the commissure between the left coronary and non-coronary valves with the formation connection with the right heart in the area of the IVS was noted. The defect was sutured by blanket stitching (prolene 4/0), the defect in the area of IVS is sutured with two U-shaped stitches (prolene 4/0) on the gaskets. The sutureless implantation of the Perceval –21 bioprosthesis was performed. Myocardial ischemia 66 min.

The early postoperative period was uneventful: the extubation of the trachea was performed 11 hours after the operation, the patient was transferred from the intensive care unit on day 2. The control EchoCG on day 6 after the operation: the peak gradient on the AV prosthesis 24 mm Hg, transprosthetic regurgitation grade 0–1, LV EF 56%, systolic pressure in PA 30 mm Hg .

As in the first observation, cardiac arrhythmias were noted (complete transverse atrioventricular block), and therefore on day 7 after the operation, the patient was transferred to another hospital in a satisfactory condition, where permanent two-chamber pacemaker was installed.

Clinical observation 3

Patient K., 70 years old, was admitted in June 2018 with complaints of dyspnea at rest and tachycardia. In April 2013, the patient underwent surgery for a combined pathology: AV replacement with the bioprosthesis Carpentier-Edwards Perimount–23, mammarocoronary anastomosis with the anterior interventricular branch of the left coronary artery and CABG of the posterior interventricular branch of the RCA. Three years after the operation, the patient was diagnosed with an infectious endocarditis of the AV prosthesis, which was manifested by hyperthermia up to 40° C, dyspnea with minimal exertion and tachycardia, and hemodynamically insignificant paraprosthetic fistula was detected during echoCG; the conservative treatment with a positive effect. Subsequently, no rises in temperature or signs of heart failure were noted. In April 2018, the patient had dyspneawith little exertion, and then at rest.

When viewed upon admission, the state was relatively satisfactory.

According to EchoCG: the shadow of the biological prosthesis in the AV position, not limited mobility of cuspids, there is a pathological mobility of the prosthesis in the area of the right coronary sinus, aortic root diameter 4.4 cm, the peak gradient on the AV prosthesis 32 mmHg., paraprosthetic regurgitation of LV grade 2-3 (paraprosthetic systolic flow in the area of right coronary sinus, paraprosthetic diastolic flow in the area of mitral-aortic contact), EDV 203 ml, LVEF 60%, local LV contractility is not impaired, the thickness of the IVS 1.3 cm, the LV posterior wall thickness 1.2 cm, the systolic pressure in the PA is 45 mm Hg. Coronary angiography: passable grafts, the distal paart of revascularized arteries is well filled. The EuroSCORE II index was 15.3%.

On the 2nd day after the hospitalization, the patient underwent an operation: repeated AV replacement with the Perceval–25 bioprosthesis under AC conditions.

From the operation protocol:

Transverse oblique aortotomy with bypass of the shunt to RCA. Xenopericardial bioprosthesis Carpentier-Edwards Perimount–23 in the position of AV. The cuspids of the valve are thickened, the mobility of cuspids is not limited. At the level of the right coronary and non-coronary sinuses, there is a paraprosthetic fistula on 1/3 of the perimeter of the base ring due to the eruption of the sutures. Residues of purple color with a diameter of 3-4 mm are found on the base ring. The AV prosthesis is excised. FR is swollen, loose. After rehabilitation and removal of all deposits, the FR was treated with iodopyrone several times in alternation with washing the left heart with an isotonic solution of sodium chloride. Blanket stitch (prolene 4/0) restored the integrity of the FR in the projection of the left coronary cusp. The sutureless xenopericardial biological prosthesis Perceval–25 was implanted. The myocardial ischemia lasted 72 min.

The postoperative period was uneventful, the extubation of the trachea was performed 16 hours after the surgery, the patient was transferred from intensive care unit on day 4 after elimination of encephalopathy. According to the control EchoCG, the AV prosthesis function was satisfactory: peak gradient 18 mm Hg, transprosthetic regurgitation grade 0–1, paraprosthetic regurgitation is not revealed. Systolic pressure in PA 35 mm Hg.

On the 8th day after the operation, the patient was discharged from the department.

DISCUSSION

A standard AV repeated prosthetic surgery is a complex procedure and is associated with an increased risk due to the presence of adhesions in the pericardial cavity, previously performed CABG in some patients, difficulties of excision of the previously implanted prosthesis, narrow AV FR and aorta [17]. All these technical difficulties affect the time of myocardial ischemia, the duration of AC, the volume of blood loss and determine the increased hospital mortality in this group of patients [18]. The choice of Perceval for repeated replacement, which implantation does not imply fixation with sutures, is explained by the desire to reduce the influence of risk factors of repeated intervention on the result of the operation.

Xenopericardial bioprosthesis Perceval S is a device where frameless bioprosthesis is taken as the basis of the valve element «Solo» [19]. The skeleton of the prosthesis consists of nitinol and is represented by 9 struts, interconnected by 2 rings, in a self-deploying anchor device, which delivers it to the site of implantation. The advantages of this type of prosthesis and implantation method include reducing the aortic clamping time, reducing the overall operation time, eliminating the need for suturing FR and related complications, such as eruption of FR and the aortic wall, making the anatomical positioning of the prosthesis convenient for narrow FR and repeated operations [16].

In the first clinical example, the previously performed AV prosthetics was complicated by the development of aortic ventricular shunt associated with the dissection of narrow FR during its decalcification. Complications of AV prosthetics with calcified aortic stenosis, such as the formation of paraprosthetic AV FR and the need for careful decalcification. During the decalcification of FR, especially when conducting an operation from the ministernotomic access, its dissection may occur more often in the area of the right coronary sinus with the RV muscle exposed. The pathological connection can be eliminated when suturing FR for implantation of the prosthesis with sutures on the gaskets from the LV side. This is almost always enough to eliminate the connection, however, with significant destruction of AV FR, there is still the danger of re-forming the pathological shunt. Performing the above manipulations can be complicated by the presence of a narrow AV FR.

The use of a biological prosthesis Perceval S, implanted using a sutereless technique, made it possible not to suture the newly destroyed FR in the area of the right coronary sinus, which secured it from possibly even greater trauma and required less time to implant the prosthesis. This was especially important in connection with the need for RCA CABG and aortic-ventricular fistula suturing. EchoCG data obtained intraoperatively and in the early postoperative period showed good hemodynamic characteristics of the AV prosthesis, the absence of aorto - ventricular and paraprosthetic regurgitation. The used re-operation scheme allowed us to obtain a good result in an elderly patient with a rare complication of the surgical treatment of calcified AV stenosis using the standard procedure.

In the 2nd clinical example, the sutureless method of implanting a bioprosthesis made it possible to avoid complications associated with the repeated suturing of narrow AV FR, and to minimize the time of myocardial ischemia.

In the 3rd observation of patient K. with a high surgical risk (EuroSCORE II 15.3%) and a tear-off valve due to past infectious endocarditis, the use of the Perceval S prosthesis made it possible to avoid re-suturing the destroyed AV FR, which also significantly reduced the time of myocardial ischemia, made the operation less traumatic and reduced the likelihood of re-formation of the paraprosthetic fistula.

According to foreign literature, the world has accumulated little experience in the use of sutureless prostheses for repeated operations on AV. Single articles report good immediate results [2, 16, 20]. Thus, a group of authors under the direction of G. Santarpino [2] conducted a study in which 83 patients with AV defect underwent the implantation of the sutureless prosthesis Perceval S, of which 13 patients had a prosthesis installed during AV repeated replacement. In one of the 13 observations presented, a permanent pacemaker was implanted in connection with the development of a complete transverse block. In our observation, the implantation of a permanent pacemaker was required in 2 patients. It should be emphasized that the development of a complete atrioventricular block with a high degree of probability was associated not with the prosthesis Perceval, but with manipulations on the FR, which took place in both cases. In the study G. Santarpino et al. as in our experience, there were no deaths or paraprosthetic regurgitation.

In the works of P. Dedeilias et al. [16] and E. Ferraria et al. [20] there are no detailed data on the results of using the technique of sutureless implantation of a biological valve in AV repeated replacement, only the possible advantages of implanting the Perceval prosthesis during repeated operations are mentioned.

It is important to emphasize that in the last of the clinical observations we presented, the Perceval prosthesis was used in infectious endocarditis. Despite the presence of a verified infection in the area of FR, there were no signs of persistent infection and dysfunction of the prosthesis in the early postoperative period after the treatment with an antiseptic and implantation of the prosthesis with biological tissue. The design and correctly selected size of the prosthesis ensured its reliable fixation in the conditions of an infected FR, which was confirmed by postoperative EchoCG data. In the experience of G. Santarpino et al. [2] all patients were re-operated in the absence of infection.

CONCLUSION

Thus, the use of an AV prosthesis with sutureless implantation in the cardiac practice allows you to make non-standard decisions in the surgical treatment of patients with various complications of previously performed AV replacement and to achieve good immediate and long-term results if AV is needed to be re-operated.

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Received on 03.10.2018

Accepted on 20.12.2018