IMMEDIATE CLINICAL RESULTS OF THE NEW BIOLOGICAL SUPPORT RING FOR CORRECTION OF MITRAL INSUFFICIENCY

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Highlights

- Clinical first experience application of a new biological closed semi-rigid ring for mitral valve annuloplasty "NEORING" (Closed Joint-Stock Company "NeoCor", Kemerovo) was evaluated.
- Intracardiac hemodynamics after the mitral valve annuloplasty with a biological semi-rigid ring "NEORING" was analyzed.

Aim	To make the first clinical experience evaluation of the new biological closed support ring for mitral valve.
Methods	26 patients (16 men, 10 women, mean age 55 [49; 62] years) with dysplastic mitral insufficiency were implanted "NEORING" biological ring for the first time from March 2020 to June 2021. The etiological factor of the defect formation in all cases was the connective tissue dysplasia. The mean functional class of heart failure before surgery was 2 [2; 3] according to NYHA, the effective regurgitant orifice (ERO) was 0.4 [0.3; 0.5], vena contracta was 0.7 [0.6; 0.8]. Ten patients received rings of 28 mm diameter, ten patients – 30 mm, six patients – 32 mm.
Results	No significant adverse events such as death from any causes, strokes, myocardial infarction, cardiac complications, bleeding, and return of regurgitation or failure of plastic surgery requiring reoperation, infective endocarditis after the intervention were observed. In two cases a permanent pacemaker was implanted due to sinus node dysfunction. At discharge all patients had no regurgitation (ERO 0), medium transvalvular gradient was 4.0 [3.0; 5.3] mm Hg. All the patients were assigned to NYHA functional class I heart failure after the surgery.
Conclusion	New biological support ring "NEORING" ("NeoCor", Kemerovo) use in the middle age group of patients showed high hemodynamic efficiency, the absence of specific complications in the early stages after the surgery. It is planned to expand the clinical material on the use of the biological ring, as well as to evaluate the long-term results in the format of a prospective, randomized trial and compare the new device with the existing ones.

Keywords Mitral valve • Support ring • Annuloplasty • Connective tissue dysplasia

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List of Acronyms

MV – mitral valve; FC – functional

Introduction

Mitral [valve] (MV) regurgitation is the most commonly occurring acquired heart valvular disease second to aortic stenosis [1]. Surgical treatment greatly improves chances of a favorable outcome for such patients, with the degenerative and secondary forms of regurgitation the probability of preserving the valve standing at 90-100%. The support ring based valve preservation technique was pioneered by A. Carpenter in 1969. [2]; since then, this procedure has seen continuous improvement. The essential component of annuloplasty is the remodeling of the fibrous valve ring using dedicated devices, i.e. support rings.

Today, cardiac surgeons has a vast array of support rings for a valvuloplasty (MV plasty) procedure offering rigidity, form and superior manufacturing materials as their key features,

Most models share the use of artificial materials in the cuff [3, 4]. However, the abundant choice of support ring designs using artificial materials makes it clear that there is no perfect option; also, a series of studies into infective endocarditis show that the use of these designs is not advised due to a high probability of disease recurrence as opposed to xenopericardial cuffs that are not known to increase such odds [5]. The research personnel at the FSBSI RICICD (Federal State Budgetary Scientific Institution 'Research Institute for Complex Issues of Cardiovascular Diseases') in collaboration with (Kemerovo-based) CJSC NeoCor's team have come up with a 'NEORING' innovative biological support ring for mitral annuloplasty being one of its kind solution in the world that helps retain the form and physiological capabilities of the MV fibrous ring along with its inherent bio-mechanical functions. The frame is made of super-elastic Nitinol with a shape memory effect and high radiopacity. The product has a natural saddle-shaped form of the MV fibrous ring and is made of a xenopericardial material reinforced with ethylene glycol diglycidyl ether and covered with anti-thrombotic surface coatings (fig. 1).

Рисунок 1. Биологическое замкнутое опорное седловидное кольцо «НЕОРИНГ»
Примечание: *изображения биологического опорного кольца для аннулопластики митрального клапана опубликованы с письменного разрешения ЗАО «НеоКор».*
Figure 1. Biological closed support saddle ring "NEORING"
Note: *the images of the biological support ring for mitral valve annuloplasty are published with the written permission of "NeoCor".*

Таблица 1. Общая характеристика пациентов, Me [Q1; Q3]
Table 1. General characteristics of patients, Me [Q1; Q3]

Показатель / Index	Значение / Value
Возраст, лет / Age, years	55 [49; 62]
Мужчины/Женщины, n / Male/Female, n	16/10
Площадь поверхности тела, м² / Body surface area, m²	1,95 [1,81; 2,16]
ФК СН по NYHA / FC NYHA of heart failure	2 [2; 3]
Регургитация МК / MV Regurgitation	4 [3; 4]
Сопутствующие заболевания / Concomitant disease, n:	
ишемическая болезнь сердца / ischemic heart disease	8
мультифокальный атеросклероз / multifocal atherosclerosis	4
хроническая обструктивная болезнь легких / chronic obstructive pulmonary disease	3
сахарный диабет / diabetes mellitus	2
фибрилляция предсердий / atrial fibrillation	5
СКФ MDRD, мл/мин/м² / GFR MDRD, ml/min/m²	91 [83; 111]

Примечание: *МК – митральный клапан; СКФ – скорость клубочковой фильтрации; СН – сердечная недостаточность; ФК – функциональный класс; NYHA – Нью-Йоркская ассоциация сердца. Me – медиана; Q1 – нижний квартиль; Q3 – верхний квартиль.*
Note: *FC – functional class; GFR – glomerular fi rate; MDRD – Modifi of diet in renal disease; MV – mitral valve; NYHA – New York Heart Association. Me – median; Q1 – lower quartile; Q3 – upper quartile.*

Project Objective: to make the first clinical experience evaluation of the innovative biological closed support ring for mitral (MV) plasty.

Materials and Methods:

A prospective analysis of surgical outcomes was made by continuous sampling on 26 patients suffering from dysplastic mitral regurgitation, who were subsequently implanted with the NEORING Biological Ring between March 2020 and June 2021. 1.

The average age of the patients is 55 [49; 62] years. In 8 patients, mitral (MV) regurgitation was aggravated by ischemic heart disease although unrelated to it; coronary angiogram revealed the hemodynamically insignificant stenosis of the coronary arteries in all the examined patients. In all cases, the etiological factor of the defect formation was the connective tissue dysplasia The mean pre-op functional class (FC) of heart failure was 2 [2; 3] according to NYHA, the effective regurgitant orifice (ERO) – 0.4 [0.3; 0.5] cm2, and vena contracta – 0.7 [0.6; 0.8].

All surgeries were performed under artificial blood circulation with CO2 insufflation being carried out as per standard practice to prevent embolic complications in the wound and myocardial protection was provided by a Custodiol® solution (Kohler Chemie, Germany). Once the leaflets and MV subvalvular apparatus were examined, the following reconstructive techniques were employed: prosthetic chords were inserted in 2 cases; the second-order chords were trans-located in 14 cases; resection techniques were applied in 16 cases; and a combination of reconstruction techniques were employed in 6 patients. In all cases, the MV plasty procedure culminated in the insertion of a biological support ring using U-shaped stitches across liners.

Initially, the MV fibrous ring was sewn over in the hinge zone using U-shaped stitches on Teflon liners followed by the attachment of the biological support reference ring by puncturing with the first needle through the xenopericardial cuff further running over the Nitinol frame from the inside and by the second needle – through the xenopericardial cuffs from the outer side of the Nitinol frame; the threads were run along parallel to each other, which made for a closer fit of the frame to the MV fibrous ring and a mitigated risk of stitches coming out through the xenopericardial cuff of the biological support ring (Fig. 2).

Ten patients were implanted with 28 mm Ø rings, another ten patients – 30 mm Ø, and six patients – 32 mm Ø. The ring sizes were correlated with the patients' body surface. The individual support ring sizing technique was not any different from the customary one. The viability of the reconstruction procedure was controlled using intraoperative transesophageal echocardiography. In five cases, MAZE IV radio-frequency biatrial ablation was performed for MV atrial fibrillation in parallel with the surgery; in two cases, the secondary tricuspid regurgitation was corrected by means of a biological tricuspid support ring.

The study was approved by the local ethics committee at the FSBSI RICICD. All patients signed an informed voluntary consent to take part in the study.

Statistical Analysis

The distribution type was checked against the Kolmogorov-Smirnov criterion. The distribution type is abnormal. Non-parametric statistics methods were used. An analysis of related variables was made using Wilcoxon's test. Data were presented in the median (Me) form and in the interquartile range [Q1; Q3]. The probability of an error of the first kind was set at 5% (0.05).

Outcomes

No cases of death, stroke, myocardial infarction, cardiac complications, bleeding, and return of regurgitation or failure of plastic surgery requiring reoperation, post-surgery infective endocarditis were observed. In two cases, a permanent pacemaker was implanted due to sinus node dysfunction. The timings of artificial blood circulation (114 [98; 128] min) and heart anoxia (75 [68; 93] min.) were different depending on the scale of intervention (table 2).

The average duration of artificial lung ventilation was 7 [7; 8] h. All patients were transferred from the intensive care unit on the following day after the operation. The number of bed days in intensive care from surgery to discharge was 10 [9; 13] days. By the time of discharge, all patients had insufficient blood circulation diminished and exercise intolerance enhanced; after the surgery, all patients were classified into NYHA functional class I heart failure (according to a six-minute walking test).

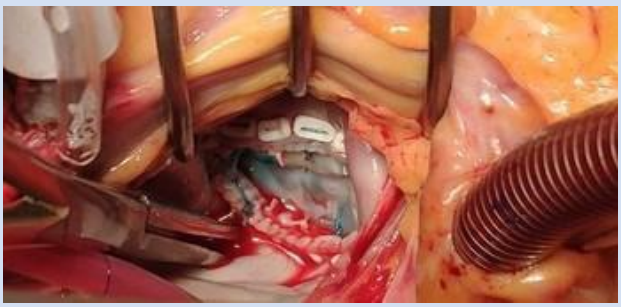

Рисунок 2. Вид биологического опорного кольца после имплантации
Figure 2. The view of the biological support ring after implantation

Таблица 2. Характеристика госпитального периода, Me [Q1; Q3]
Table 2. Characteristics of the hospital period, Me [Q1; Q3]

Показатель / Index	Значение / Value
Время ИК, мин / Time AC, min	114 [98; 128]
Время окклюзии аорты, мин / Aortic occlusion time, min	75 [68; 93]
Размер имплантированного опорного кольца / Ring size, n (%): 28 мм / mm 30 мм / mm 32 мм / mm	 10 (38) 10 (38) 6 (23)
Длительность ИВЛ, ч / Duration AVL, h	7 [7; 8]
Потребность в инотропной поддержке / Inotropic support, n (%): моно / mono двойная / double	 8 (61,5) 2 (15,4)
Длительность инотропной поддержки, ч / Inotropic support duration, h	12 [7; 18]
Количество койко-дней нахождения в реанимации / Bed-days in intensive care	1 [1; 1]
Койко-дней до выписки с момента операции / Bed-days from the moment of surgery to discharge	10 [9; 13]

Примечание: *ИВЛ – искусственная вентиляция легких; ИК – искусственное кровообращение. Me – медиана; Q1 – нижний квартиль; Q3 – верхний квартиль.*
Note: *AVL – artifi ventilation of the lungs; AC – artifi circulation; Me – median; Q1 – lower quartile; Q3 – upper quartile.*

At the time of discharge, all patients had no regurgitation (ERO 0). The medium transvalvular gradient was 4.0 [3.0; 5.3] mm Hg.

A positive trend in the remodeling of the cardiac chambers and pressure reduction were observed in the pulmonary circuit (table 3).

Discussions

Mitral regurgitation is the most commonly diagnosed heart valve disease second only to the aortic valve stenosis and most frequently occurs in the overall population [6]. In developed countries, mitral regurgitation is most commonly blamed on degenerative changes in the MV. Two leading types of connective tissue degeneration, Barlow's disease and fibroelastic deficiency are associated with types I and II of mitral insufficiency according to A. Carpentier's classification [1, 7].

Severe dysplastic mitral regurgitation carries an unfavorable prognosis. Following an extended asymptomatic period, severe dysplastic mitral regurgitation develops into the symptomatic stage accompanied by left ventricle dilatation followed by left ventricular failure, left atrium dilatation, and high pulmonary hypertension. Timely correction of mitral regurgitation helps get longevity back on track with that of the healthy population [8]. A number of highly effective MV reconstruction techniques have been engineered: French correction (A. Carpentier, 1983 [9]), Respect Rather Than Resect (P. Perier, 2008 [10]) and American correction (M. Lawrie, 2009 [11]). One of the critical and mandatory steps in these techniques is the fixation of the compromised native fibrous ring of the mitral valve with a bespoke anatomically compatible design dubbed as an annuloplasty support ring. The usage of support rings should follow two primary objectives, i.e. (the) resizing (of the fibrous ring) and reshaping (getting the deformed fibrous ring back its original shape), however not all rings are capable to restore the peculiar 3D-configuration of the mitral valve fibrous ring.

R. Masaaki and alt. [3] have demonstrated the efficiency of repairing the 3-D saddle-shaped form of the mitral valve following the annuloplasty procedure by semi-rigid (Carpentier-Edwards Physio II ring) and rigid (St. Jude Medical Rigid Saddle Ring) closed support rings, albeit with some lost dynamics of valve morphometrics in various cardiac cycle phases. Memo 3D semi-rigid support rings have been proven to be highly efficient in retaining the physiological dynamics of the MV fibrous ring and leaflet apparatus, albeit without the capability to make an anatomical saddle shaped form.

In A. V. Afanasiev's study [12], the comparison of the D ring semi-rigid closed support ring (manufactured by CJSC NPP MedInzh, Pensa, Russia) and the C flex flexible half-ring (band) (manufactured by CJSC NPP MedInzh, Pensa, Russia) employed in the task of correcting dysplastic mitral regurgitation has demonstrated that the use of a certain type of a support ring has nothing to do with the survival rate of patients or the heart failure functional class in a long-term observation period.

Even what with a myriad of completed clinical studies on the use of different types of support rings to correct dysplastic mitral regurgitation, no recommendations for the choice of a support ring at various etiologies of mitral regurgitation have yet been presented due to the lack of solid evidence.

Two basic trends are identifiable from the evolution of support ring design: the reshaping of the original spatial structure of the MV fibrous ring and the restoration of its physiological mobility in the course of the cardiac cycle. These trends consistently manifest themselves in the design of both rigid saddle-shaped rings illustrated by Rigid Saddle Ring (St. Jude Medical) in constructing the MV anatomical configuration and MEMO 3D semi-rigid support rings (LivaNova and Sorin Group) in providing the dynamic adaptation of a mitral and papillary continuum under various cardiac cycle phases. Therefore, the problem of creating a product combining all the detailed

Таблица 3. Показатели ЭхоКГ, Me [Q1; Q3]
Table 3. Indicators of EchoCG, Me [Q1; Q3]

Показатель / Index	До операции / Before surgery	При выписке / At discharge	p
КДР, см /EDD, cm	6,2 [5,8; 6,5]	5,6 [5,0; 6,0]	0,003
КСР, см / ESD, cm	4,0 [3,5; 4,6]	3,9 [3,4; 4,3]	0,086
КДО, мл / EDV, cm	194 [167; 216]	142 [116; 177]	0,003
КСО, мл / ESV, cm	70 [51; 97]	58 [47; 83]	0,086
ФВ ЛЖ / LV EF, %	64 [61; 69]	53 [52; 61]	0,050
ЛП, см / LA, cm	5,0 [4,8; 6,0]	4,6 [4,2; 5]	0,004
ПП, см / RA, cm	5,0 [4,5; 5,3]	4,6 [4,1; 4,8]	0,086
СДЛА, мм рт. ст. / SPPA, mm Hg	40 [33; 50]	27 [23; 36]	0,116
МЖП, см / IVS, cm	1,0 [1,0; 1,0]	1,0 [1,0; 1,0]	0,655
ЗСЛЖ, см / PWLV, cm	1,0 [1,0; 1,0]	1,0 [1,0; 1,0]	0,655
ERO, см/cm	0,4 [0,3; 0,5]	–	–
Vena contracta, см / Vena cotracta, cm	0,7 [0,6; 0,8]	–	–
Регургитация МК / Regurgitation MV	4 [3; 4]	Не выявлена	–
Vср., см/с / Vmean, cm/s	–	97 [71; 105]	–
Pср., мм рт. ст. / Pmean, mm Hg	–	4,0 [3,0; 5,3]	–

Примечание: *ЗСЛЖ – задняя стенка левого желудочка; КДО – конечный диастолический объем; КДР – конечный диастолический размер; КСО – конечный систолический объем; КСР – конечный систолический размер; ЛП – левое предсердие; МЖП – межжелудочковая перегородка; МК – митральный клапан; ПП – правое предсердие; СДЛА – систолическое давление легочной артерии; ФВ ЛЖ – фракция выброса левого желудочка; ERO – эффективная площадь регургитационного отверстия. Me – медиана; Q1 – нижний квартиль; Q3 – верхний квартиль.*

Note: *PWLV – posterior wall of the left ventricle; EDV – end-diastolic volume; EDD – end-diastolic dimension; ESV – end-systolic volume; ESD – end-systolic dimension; LA – left atrium; IVS – interventricular septum; MV – mitral valve; RA – right atrium; SPPA – systolic pressure of the pulmonary artery; LV EF – left ventricular ejection fraction; ERO – effective area of the regurgitant orifice; Me – median; Q1 – lower quartile; Q3 – upper quartile.*

features has remained unsolved.

This study presents the immediate clinical evidence of the use of 'NeoRing' innovative support ring bringing together such features as a closed support portion enabling accurately securing the fibrous ring within a specified diameter entailing no risk of further dilatation; a frame made of high radiopacity nuclide titanium having a shape memory effect; an anatomically saddle shaped support ring adapting to various cardiac cycles allowing for physiological three-dimensional deformation, thereby mitigating the impact on transmittal flows by eliminating an excessively narrowed mitral-aortic angle and diminishing the post-loading of the left atrium; xenopericardial casing preserved with anti-thrombotic diglycidyl ether coating inducing faster endothelization in the recipient's body and mitigating the risk of thromboembolic events in the early post-operative period. The study results bring to light a positive trend in remodeling the cardiac chambers in the early postoperative period and the absence of specific complications inherent in reconstructive surgeries (neo-plasties), including the MV annuloplasty. The study published by L. Eric and alt. [13] shows the cyclic deformation of the MV put through annuloplasty with a securing support ring according to the classic technique with separate stitches using no gaskets; the telltale cyclic changes in the form of the fibrous ring on the front leaflet, the saddle-shaped valve, the filling aorta and the offset of the fibrous triangle, i.e. the factors leading to increasingly intense pressure on the stitches in the mitral-aortic contact area, which, in turn, rather than to severing the thread itself due to its high strength smoothens the path for the stitching to come through the fabric of the MV hinge zone. Giving due consideration to these things, we have opted for using U-shaped stitches on teflon liners to prevent the support ring separation from coming off; moreover, the adaptive ring structure evenly distributes the load over on the stitches.

Conclusion

The employment of the 'NEORING' new biological support ring (CJSC NeoCor, Kemerovo) in patients suffering from dysplastic mitral regurgitation has showed high hemodynamic efficiency and no specific complications in the early post-surgery stages. Going forward, we have plans to expand the clinical evidence on the use of the biological ring, evaluate emerging long-term data through a prospective, randomized study and compare the new product with the existing models.

Conflicts of Interest

I. V. Dvadtsatov states that there is no conflict of interest. A.V. Evtushenko states that there is no conflict of interest. A. N. Stasev states that there is no conflict of interest. A.V. Sotnikov states that there is no conflict of interest. R. N. Komarov states that there is no conflict of interest. L. S. Barbash is the editor-in-chief of 'Complex Issues of Cardiovascular Diseases' journal.

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Вклад авторов в статью

ДИВ – анализ и интерпретация данных исследования, корректировка статьи, утверждение окончательной версии для публикации, полная ответственность за содержание

ЕАВ – получение и интерпретация данных исследований, корректировка статьи, утверждение окончательной версии для публикации, полная ответственность за содержание

САН – получение и интерпретация данных исследований, корректировка статьи, утверждение окончательной версии для публикации, полная ответственность за содержание

САВ – интерпретация данных исследований, корректировка статьи, утверждение окончательной версии для публикации, полная ответственность за содержание

КРН – интерпретация данных исследований, корректировка статьи, утверждение окончательной версии для публикации, полная ответственность за содержание

БЛС – интерпретация данных исследований, корректировка статьи, утверждение окончательной версии для публикации, полная ответственность за содержание

Author Contribution Statement

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