

SOME INNOVATIVE TECHNOLOGIES FOR THE CORRECTION OF VALVULAR HEART DISEASES. REVIEW

Sagatov I.Y.

orcid.org/0000-0002-4668-1513

Kudaibergen A.B.

orcid.org/0000-0002-2725-7530

Momynov B.M.

orcid.org/0000-0002-6008-0298

Corresponding author:

Momynov B.M. – Resident of Cardiac Surgery Department, JSC "A.N. Syzganov National Scientific Center for Surgery".

E-mail: bakhytzhhan.momynov@gmail.com

Conflict of interest

The authors declare that they have no conflicts of interest

Keywords

mitral valve, correction

Sagatov I.Y., Kudaibergen A.B., Momynov B.M.

JSC «A.N. Syzganov National Scientific Center for Surgery», Almaty, Kazakhstan

Abstract

Valve defects or congenital/acquired heart defects are damage to the valve and/or subvalvular structures, which leads to impaired hemodynamics and the development of heart failure. Asymptomatic valvular heart disease is present in 2.5% of the population; with age, this figure rises to 13%. In the absence of permanent treatment, lesions of the heart valves significantly reduce the quality and duration of life. The European Society of Cardiology (ESC) and the American Heart Association (AHA) regularly review the effectiveness of new surgical treatments and reflect their findings in international guidelines. Today, minimally invasive surgery is the most effective and safe way to treat patients with valvular heart disease. The article presents two new methods for the treatment of valvular heart disease. Transapical mitral valve repair on a beating heart with neochoord implantation (TOP-MINI) is a new MVP option that has been approved for patients with severe mitral regurgitation due to prolapse of the leaflet (s) or chord (grades 2-4). The new procedure with the NeoChord DS1000 device results in a significant reduction in mitral regurgitation and in reverse remodeling of the left ventricle and left atrium after 6 months of follow-up. Also reviewed is Minimally Invasive Aortic Valve Replacement (MAVR), which has been shown to be beneficial in improving patient satisfaction by minimizing pain and earlier recovery. Sutureless valves are preferred over traditional aortic valve replacement (AVR) due to the reduced operation time and the need for blood transfusion. The Perceval valve (Sorin, Sallugia, Italy) is a self-expanding bovine pericardial prosthesis placed in a nitinol stent designed to facilitate aortic valve implantation. A systematic review and meta-analysis demonstrated that the early clinical and hemodynamic characteristics of the Perceval valve are satisfactory and comparable to those of conventional AVRs.

This literature review was carried out in accordance with the PRISM statement. The databases searched in this review included Pubmed, Web of Science, Scopus and Cochrane databases for systematic reviews.

Жүректің қақпақшалы ауруын түзетудің инновациялық кейбір технологиялары. Әдебиет шолуы

Сағатов І.Е., Құдайберген А.Б., Момынов Б.М.

«А.Н. Сызғанов атындағы Ұлттық ғылыми хирургия орталығы» АҚ, Алматы қ., Қазақстан

Аңдатпа

Қақпақшалардың жүре пайда болған немесе туа біткен ақаулары – бұл гемодинамиканың бұзылуына және жүрек жеткіліксіздігінің дамуына әкелетін қақпақшалардың және/немесе қақпақша асты құрылымдардың зақымдануы. Асимптоматикалық жүрек ақаулары халықтың 2,5% - ында кездеседі, жасына қарай бұл көрсеткіш 13% - ға дейін артады. Жүрек клапандарының зақымдануын тұрақты емдеу болмаған жағдайда, өмір сүру сапасы мен ұзақтығын айтарлықтай төмендетеді. Еуропалық кардиология қоғамы (Еуропалық Кардиология қоғамы, ESC) және Американдық жүрек қауымдастығы (American Heart Association, AHA) емдеудің жаңа хирургиялық әдістерінің тиімділігін үнемі зерттеп отырады және халықаралық ұсыныстарда өз зерттеулерінің нәтижелерін көрсетеді. Бүгінгі таңда минималды инвазивті хирургия жүрек қақпақшасы бар науқастарды емдеудің ең тиімді және қауіпсіз әдісі болып табылады. Мақалада жүрек клапанының патологиясын емдеудің екі жаңа әдісі келтірілген. Неохордты (TOP-MINI) имплантациялау арқылы жұмыс істейтін жүректегі митральды қақпақшаны трансапикальды қалпына келтіру - бұл PMK-нің жаңа нұсқасы, ол жапырақтың немесе аккордтың (2-4 градус) пролапсына байланысты ауыр митральды жеткіліксіздігі бар науқастар үшін мақұлданған. NeoChord ds1000 құрылғысы бар жаңа процедура 6 айлық бақылаудан кейін митральды жеткіліксіздіктің және сол жақ қарыншаның және сол жақ атриумның қайта қалпына келу дәрежесінің айтарлықтай төмендеуіне әкеледі. Сондай-ақ, аорта қақпақшасын (MAVR) минималды инвазивті ауыстыру әдісі қарастырылған, ол ауырсынуды азайту және ертерек қалпына келтіру арқылы пациенттердің қанағаттануын арттырудың артықшылығын көрсетті. Жіксіз клапандар операция уақытын қысқарту және қан құю қажеттілігі есебінен дәстүрлі аорта қақпағын (AVR) ауыстырған жөн. Perceval клапаны (Sorin, Саллуджия, Италия) - бұл аорта қақпақшасын имплантациялауды жеңілдету үшін жасалған нитинол стентіне орнатылған өзін-өзі кеңейтетін бұқа перикардты протез. Жүйелі шолу және мета-анализ Perceval клапанының ерте клиникалық және гемодинамикалық сипаттамалары қанағаттанарлық және қарапайым AVR-мен салыстырылатындығын көрсетті.

Бұл әдебиетті шолу PRISM мәлімдемесіне сәйкес жүргізілді. Осы шолуда ізделген дерекқорларға жүйелі шолулар үшін Pubmed, Web of Science, Scopus және Cochrane дерекқорлары кірді.

Түйін сөздер

митральды қақпақша, түзету

Хат алысатын автор:

Момынов Б.М. – кардиохирургия бөлімінің дәрігер-резиденті, «А.Н. Сызғанов атындағы Ұлттық ғылыми хирургия орталығы» АҚ.

E-mail: bakhytzhhan.momynov@gmail.com

Мүдделер қақтығысы

Авторлар мүдделер қақтығысының жоқтығын мәлімдейді

Некоторые инновационные технологии коррекции клапанных пороков сердца. Обзор литературы

Сагатов И.Е., Кудайберген А.Б., Момынов Б.М.

АО «Национальный научный центр хирургии им. А.Н. Сызганова», г. Алматы, Казахстан

Аннотация

Пороки клапанов или врожденные/приобретенные пороки сердца – это поражение клапана и/или подклапанных структур, которое приводит к нарушению гемодинамики и развитию сердечной недостаточности. Бессимптомные клапанные пороки сердца присутствуют у 2,5% населения, с возрастом эта цифра возрастает до 13%. При отсутствии постоянного лечения поражения клапанов сердца существенно снижает качество и продолжительность жизни. Европейское общество кардиологов (European Society of Cardiology, ESC) и Американская кардиологическая ассоциация (American Heart Association, АНА) регулярно изучают эффективность новых хирургических методов лечения и отражают результаты своих исследований в международных рекомендациях. На сегодняшний день минимально инвазивная хирургия является наиболее результативным и безопасным способом лечения пациентов с клапанными пороками сердца. В статье представлены два новых метода по лечению клапанной патологии сердца. Трансапикальное восстановление митрального клапана на работающем сердце с имплантацией неохорды (TOP-MINI) - это новый вариант ПМК, который был одобрен для пациентов с тяжелой митральной недостаточностью из-за пролапса створки (листов) или хорды (2-4 степени). Новая процедура с устройством NeoChord DS1000 приводит к значительному снижению степени митральной недостаточности и обратного ремоделирования левого желудочка и левого предсердия через 6 месяцев наблюдения. Также рассмотрен метод минимально инвазивной замены аортального клапана (MAVR), которая продемонстрировала преимущество в отношении повышения удовлетворенности пациентов за счет минимизации боли и более раннего выздоровления. Бесшовные клапаны предпочтительнее традиционной замене аортального клапана (AVR) за счет сокращения времени операции и необходимости переливания крови. Клапан Perceval (Sorin, Саллуджия, Италия) - это саморасширяющийся протез из бычьего перикарда, установленный в нитиноловый стент, разработанный для упрощения имплантации аортального клапана. Систематический обзор и метаанализ продемонстрировали, что ранние клинические и гемодинамические характеристики клапана Perceval являются удовлетворительными и сопоставимы с таковыми у обычных AVR.

Этот обзор литературы был проведен в соответствии с заявлением PRISM. Базы данных, в которых проводился поиск в этом обзоре, включали Pubmed, Web of Science, Scopus и Cochrane для систематических обзоров.

Автор для корреспонденции:
Момынов Б.М. – врач-резидент
отделения кардиохирургии, АО «На-
циональный научный центр хирургии
им. А.Н. Сызганова».
E-mail:
bakhytzhn.momynov@gmail.com

Конфликт интересов
Авторы заявляют об отсутствии
конфликта интересов

Ключевые слова
митральный клапан, коррекция

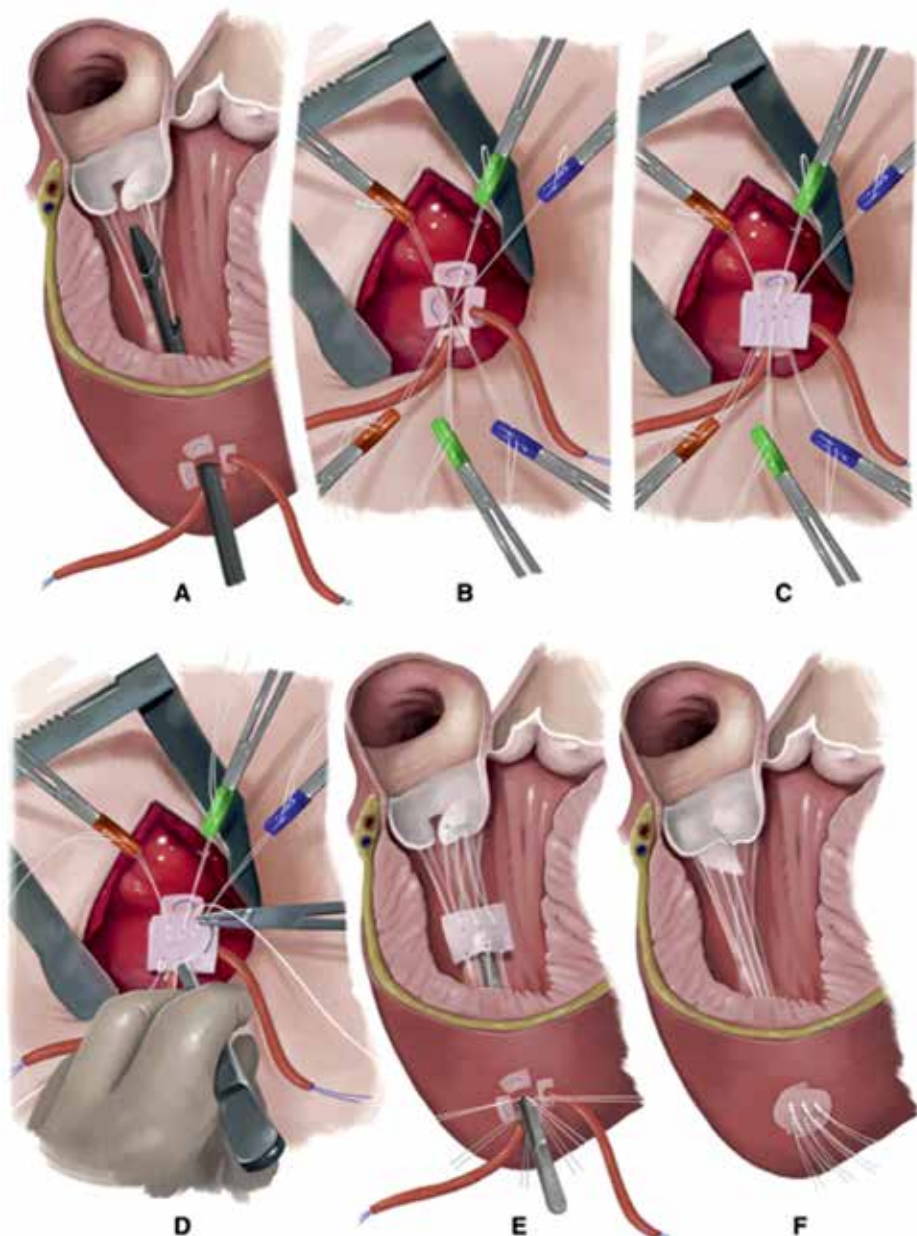
Relevance

Valvular disease or congenital/acquired heart disease are lesions of the valve and/or subvalvular structures that leads to impaired hemodynamics and the development of heart failure. Asymptomatic valvular heart disease are present in 2.5% of the population with age this figure increases to 13%. In the absence of permanent treatment of heart valve lesions significantly reduces the quality and duration of life. The European Society of Cardiology (ESC) and the American Heart Association (AHA) regularly study the effectiveness of new surgical methods of treatment and reflect the results of their research in international recommendations. For today minimally invasive surgery is the most effective and safe way to treat patients with valvular heart disease. New methods of correction that can be developed in Kazakhstan for the general development of cardiac surgical care to the population of the country. This literature review was carried out in accordance with the PRISM statement. The databases searched in this review included Pubmed, Web of Science, Scopus and Cochrane databases for systematic reviews.

The first method

The method is a transapical restoration of the mitral valve on a working heart with implantation of a neochord (TOP-MINI) - this is a new version of the MVR that has been approved for patients with severe mitral insufficiency due to prolapse of the leaf or chord (2-4 degrees). The procedure is performed using the NeoChord DS1000 system (NeoChord, Inn., Eden Prairie, MN) under the control of direct 2D and 3D transesophageal echocardiography (TEE) both for implantation and for adjusting the tension of the neochord. According to research at a hospital in Padua, Italy, from November 2013 to December 2014. During this period 111 patients were examined. The mechanism of MR development was primary or degenerative in 96 patients (86%) and secondary or functional in 12 patients (11%). Among 96 patients with primary MR, isolated posterior leaf prolapse (PML) was evident in 72 patients (75%), anterior leaf prolapse (AML) - in 13 cases (14%) and disease of both leaflets - in 11 (11%). Of the patients with primary MR Neochord implantation was performed in 49 cases (51%), while traditional surgical replacement of MVR or MV was performed in 6 (6%). Currently 16 patients (17%) are listed for traditional open heart

A, Insertion of the NeoChord DS1000 device (NeoChord, Inc, Eden Prairie, Minn) through a left minithoracotomy and a posterolateral ventriculotomy to sequentially release 3 expanded polytetrafluoroethylene chords to the free edge of the prolapsing A2. B, The loop and the end of each single expanded polytetrafluoroethylene chord are secured with colored mosquito surgical hemostat forceps. C, The loop and the end of each neochord are then secured to one of the long sides of a properly shaped rectangular pericardial patch. D, The chords attached to the anterior leaflet are now looped, and 3 more chords are then sutured to the other long side of the patch, which becomes the new free edge of the anterior mitral leaflet. E, The patch is then hoisted, driven with the help of forceps, inside the left ventricle by gently pulling on the 3 neochords, until it is positioned against the ventricular side of the anterior leaflet. F, The final result with the new augmented anterior leaflet. (Figure designed by Fabrizio Lavezzi.)
<https://doi.org/10.1016/j.jtcvs.2019.02.027>



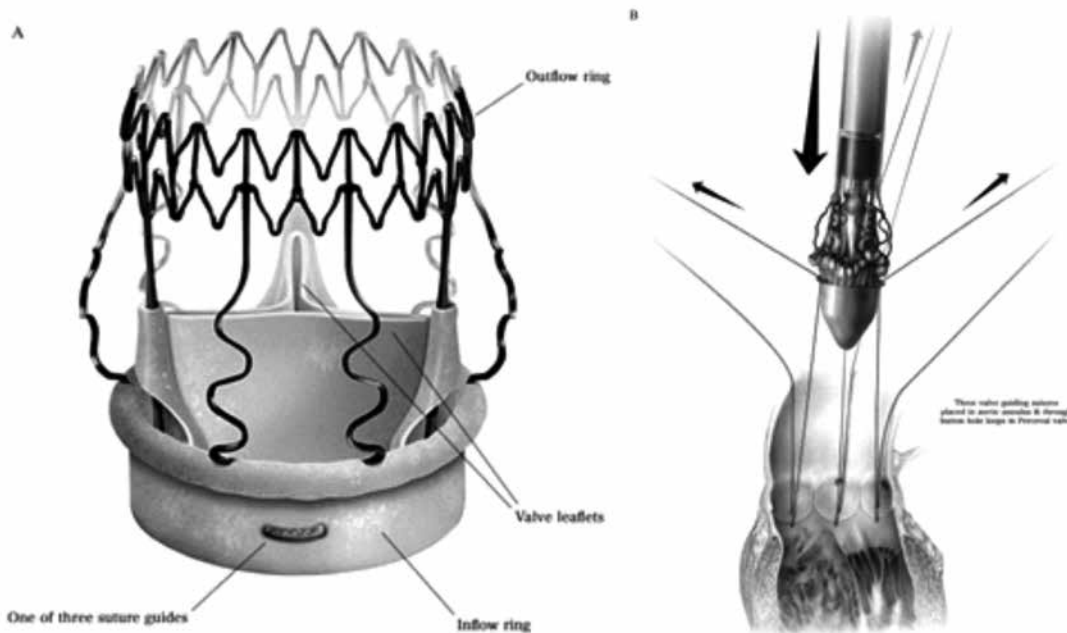
surgery, while 19 (20%) are scheduled for Neochord implantation. Six patients (6%) were treated with medication because MR was not serious enough to require intervention.

According to the Department of Cardiac Surgery, Medicover Hospital, Warsaw, Poland. Twenty-one patients with severe mitral insufficiency due to posterior valve prolapse (81% male; average age: 60.7 years \pm 12.7 years) underwent surgery on the NeoChord DS1000 system. There were 12 (57.1%) patients with type A (isolated central prolapse/flail), 8 (38.1%) patients with type B (multi-segment disease) and 1 (4.8%) patient with type C (posterior/paracommissural region) prolapse MV. A pathological leaflet was available in 12 (57.1%) patients. The average number of neochords was 3 (2-6). Echocardiography was used to evaluate the morphology

of the left heart and the degree of MR before and 6 months after chord implantation. Early success of the procedure was achieved in 100% of patients. At 6-month follow-up, minor mitral insufficiency (traces and mild) was detected in 17 (81.0%) patients, moderate MR - in 4 (19.0%) patients; the average values of the left sections of the size and volume, mitral E and E' velocity of the lateral annular space MV significantly decreased.

The second method

Minimally invasive aortic valve replacement (MAVR) has taken advantage of satisfaction by minimizing pain and earlier recovery. Sutureless valves are preferred over traditional aortic valve replacement (AVR) due to the reduction in surgery time and the need for transfusion.



Source: Aortic Valve Replacement Using a Perceval Sutureless Aortic Bioprosthesis David Heimansohn, MD, and Sina Moainie, MD; <https://doi.org/10.1053/j.optechst-cvs.2017.09.004>

The Perceval valve (Sorin, Sallugia, Italy) is a self-expanding bovine pericardial prosthesis placed in a nitinol stent designed to facilitate aortic valve implantation. This meta-analysis assesses the clinical, hemodynamic outcomes and survival of the sutureless Perceval.

After applying the inclusion and exclusion criteria, 14 out of 66 relevant articles were selected for evaluation. Of these 14 studies, 2505 patients were enrolled. Current data on the Perceval valve in aortic valve disease are limited to observational studies only. Minimally invasive surgery was performed in 976 patients, of which 336 - through the right anterior thoracotomy. The most commonly used Perceval M and L seamless valves, 782 and 770, respectively. Serious adverse event rates included 30-day mortality (0 to 4.9%), cerebrovascular accident (0 to 3%), permanent pacemaker insertion (0 to 17%), moderate to severe paravalvular leakage (0 up to 8.6%) and reoperation (from 0 to 4.8%). The postoperative mean aortic valve gradient ranged

from 9 to 15.9 mm Hg, and the postoperative NYHA class I or II ranged from 82 to 96%. Annual survival rates ranged from 86% to 100%; and 5-year survival rates ranged from 71.3% to 85.5% in two studies.

Conclusions

The new procedure with the NeoChord DS1000 device is possible in properly selected patients and results in a significant reduction in mitral regurgitation and in reverse remodeling of the left ventricle and left atrium after 6 months of follow-up.

A systematic review and meta-analysis demonstrated that the early clinical and hemodynamic characteristics of the Perceval valve are satisfactory and comparable to those of conventional AVRs. However, long-term data on the longevity and hemodynamics of the Perceval valve are somewhat limited. Large-scale randomized trials are recommended to accurately assess the long-term stability and complications associated with the Perceval valve.

References

1. L. H. Ling, M. Enriquez-Sarano, J. B. Seward, J. Tajik, H. V. Schaff, K. R. Bailey, R. L. Frye, and A. J. Tajik, "Clinical outcome of mitral regurgitation due to flail leaflet," *N. Engl. J. Med.* 335(19), 1417–1423 (1996).
2. E. Hayek, C. N. Gring, and B. P. Griffin, "Mitral valve prolapse," *Lancet* 365(9458), 507–518 (2005).
3. L. A. Freed, D. Levy, R. A. Levine, M. G. Larson, J. C. Evans, D. L. Fuller, B. Lehman, and E. J. Benjamin, "Prevalence and clinical outcome of mitral valve prolapse," *N. Engl. J. Med.* 341(1), 1–7 (1999).
4. R. R. Moss, K. H. Humphries, M. Gao, C. R. Thompson, J. G. Abel, G. Fradet, and B. I. Munt, "Outcome of mitral valve repair or replacement: A comparison by propensity score analysis," *Circulation* 108, 1190–1197 (2003).
5. P. Bajona, W. E. Katz, R. C. Daly, K. J. Zehr, and G. Speziali, "Beating-heart, off-pump mitral valve repair by implantation of artificial chordae tendinae: An acute in vivo animal study," *J. Thorac. Cardiovasc. Surg.* 137(1), 188–193 (2009).
6. I. Bahar, A. Akgul, M. A. Ozatik, K. M. Vural, A. E. Demirbag, M. Boran, and O. Tasdemir, "Acute renal failure following open heart surgery: Risk factors and prognosis," *Perfusion* 20(6), 317–322 (2005).
7. R. Freeman, B. King, and M. H. Hambling, "Infective

- complications of open-heart surgery and the monitoring of infections by the NBT test," *Thorax* 28(5), 617–621 (1973).
8. M. F. Newman, J. P. Mathew, H. P. Grocott, G. B. Mackensen, T. Monk, K. A. Welsh-Bohmer, J. A. Blumenthal, D. T. Laskowitz, and D. B. Mark, "Central nervous system injury associated with cardiac surgery," *Lancet* 368(9536), 694–703 (2006).
 9. A. Iribarne, R. Easterwood, E. Y. H. Chan, J. Yang, L. Soni, M. J. Russo, C. R. Smith, and M. Argenziano, "The golden age of minimally invasive cardiothoracic surgery: Current and future perspectives," *Future Cardiol.* 7(3), 333–346 (2011).
 10. <http://www.neochord.com/> for NeoChord DS1000.
 11. T. Feldman, E. Foster, M. Qureshi, B. Whisenant, J. Williams, D. Glower, and L. Mauri, "TCT-788 the EVEREST II randomized controlled trial (RCT): Three year outcomes," *J. Am. Coll. Cardiol.* 60(17), B229–B230 (2012). *Medical Physics*, Vol. 42, No. 1, January 2015, 468.
 12. <http://www.abbottvascular.com/int/mitraclip.html#overview> for MitraClip percutaneous mitral valve repair system.
 13. <http://www.mitralign.com/themitralignsystem> for the mitralign system.
 14. J. Harnek, J. G. Webb, K.-H. Kuck, C. Tschope, A. Vahanian, C. E. Buller, S. K. James, C. P. Tifenbacher, and G. W. Stone, "Transcatheter implantation of the MONARC coronary sinus device for mitral regurgitation: 1- year results from the EVOLUTION phase I study (clinical evaluation of the Edwards lifesciences percutaneous mitral annuloplasty system for the treatment of mitral regurgitation)," *JACC: Cardiovasc. Interv.* 4(1), 115–122 (2011).
 15. C. A. Linte, J. White, R. Eagleson, G. M. Guiraudon, and T. M. Peters, "Virtual and augmented medical imaging environments: Enabling technology for minimally invasive cardiac interventional guidance," *IEEE Rev. Biomed. Eng.* 3, 25–47 (2010).
 16. G. M. Guiraudon, D. L. Jones, D. Bainbridge, and T. M. Peters, "Mitral valve implantation using off-pump closed beating intracardiac surgery: A feasibility study," *Interact. Cardiovasc. Thorac. Surg.* 6(5), 603–607 (2007).
 17. J. Ender and S. Sgouropoulou, "Value of transesophageal echocardiography (TEE) guidance in minimally invasive mitral valve surgery," *Ann. Cardiothorac. Surg.* 2(6), 796–802 (2013).
 18. Brown JM, O'Brien SM, Wu C, et al. Isolated aortic valve replacement in North America comprising 108,687 patients in 10 years: changes in risks, valve types, and outcomes in the Society of Thoracic Surgeons National Database. *J Thorac Cardiovasc Surg* 2009;137:82-90.
 19. Flameng W, Herregods MC, Hermans H, et al. Effect of sutureless implantation of the Perceval S aortic valve bioprosthesis on intraoperative and early postoperative outcomes. *J Thorac Cardiovasc Surg* 2011;142:1453-7.
 20. Concistre G, Santarpino G, Pfeiffer S, et al. Two alternative sutureless strategies for aortic valve replacement: a two-center experience. *Innovations (Phila)* 2013;8:253-7.
 21. Lorusso R, Gelsomino S, Renzulli A. Sutureless aortic valve replacement: an alternative to transcatheter aortic valve implantation? *Curr Opin Cardiol* 2013;28:158-63.
 22. Martens S, Zierer A, Ploss A, et al. Sutureless Aortic Valve Replacement via Partial Sternotomy. *Innovations (Phila)* 2010;5:12-5.
 23. Sadowski J, Kapelak B, Pfitzner R, et al. Sutureless aortic valve bioprosthesis '3F/ATS Enable'--4.5 years of a single-centre experience. *Kardiol Pol* 2009;67:956-63.
 24. Santarpino G, Pfeiffer S, Concistră G, et al. The Perceval S aortic valve has the potential of shortening surgical time: does it also result in improved outcome? *Ann Thorac Surg* 2013;96:77-81; discussion 81-2.
 25. Cao C, Ang SC, Indraratna P, et al. Systematic review and meta-analysis of transcatheter aortic valve implantation versus surgical aortic valve replacement for severe aortic stenosis. *Ann Cardiothorac Surg* 2013;2:10-23.
 26. Vahanian A, Otto CM. Risk stratification of patients with aortic stenosis. *Eur Heart J* 2010;31:416-23.
 27. Leon MB, Smith CR, Mack M, et al. Transcatheter aortic-valve implantation for aortic stenosis in patients who cannot undergo surgery. *N Engl J Med* 2010;363:1597-607.