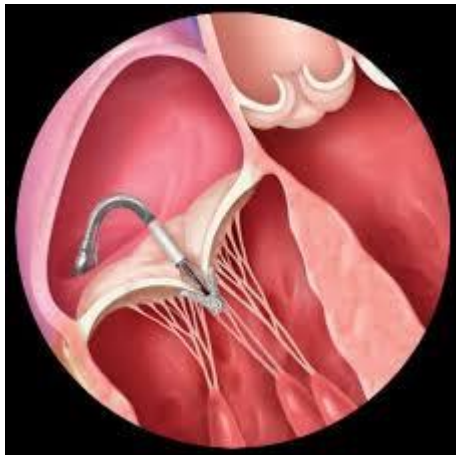
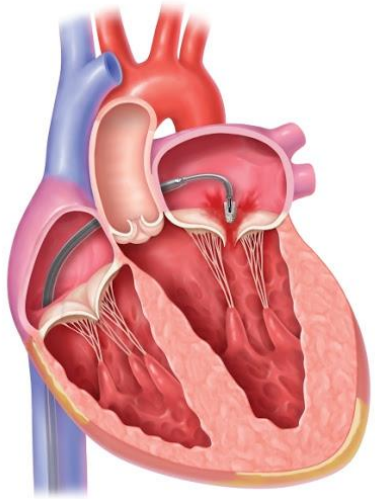
UNIVERSITÄT LEIPZIG
Medizinische Fakultät





HERZZENTRUM LEIPZIG

Эндоваскулярное лечение хронической митральной и трикуспидальной недостаточности

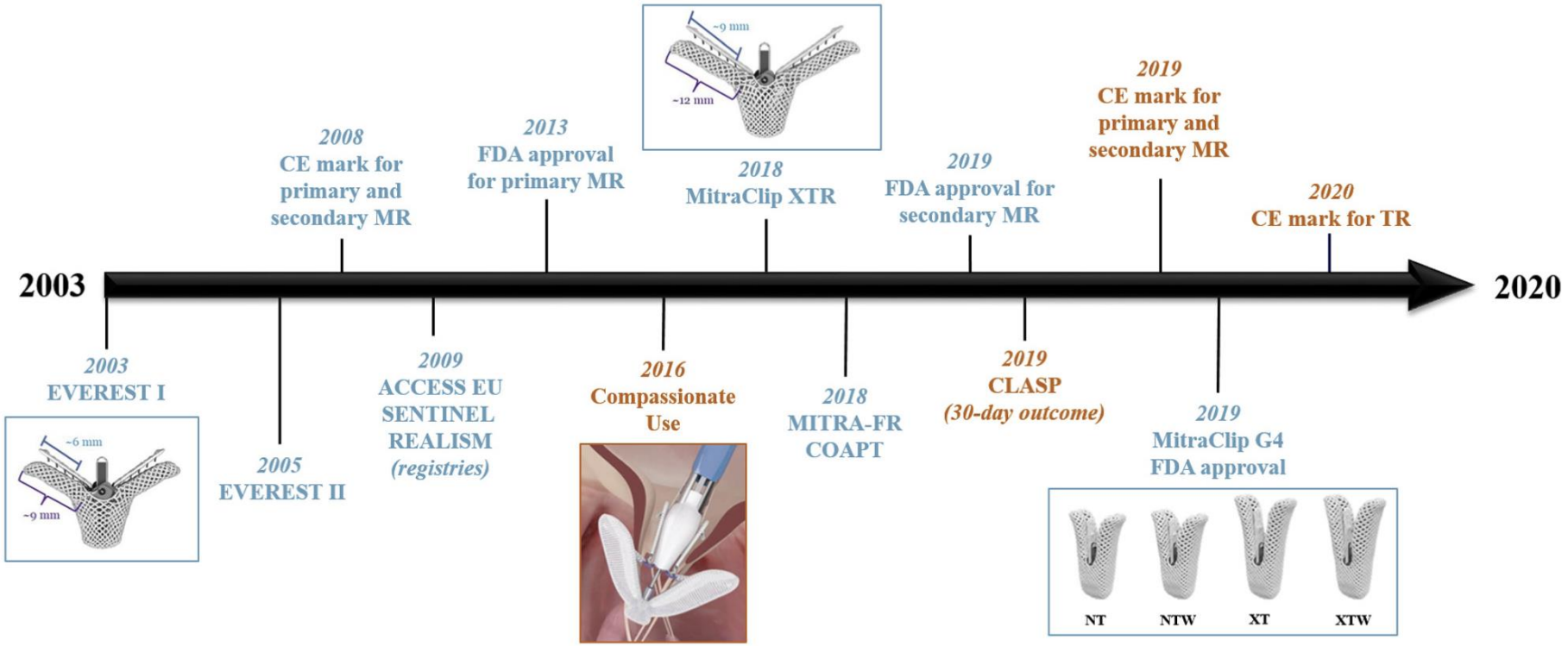
Профессор Сергей Леонтьев

25 лет

ИЮНЬСКАЯ КОНФЕРЕНЦИЯ В КАРДИОКЛИНИКЕ

Интервенционное лечение МН

Edge-to-Edge



2022

MitraClip Gen 4

NT NTW XT XTW

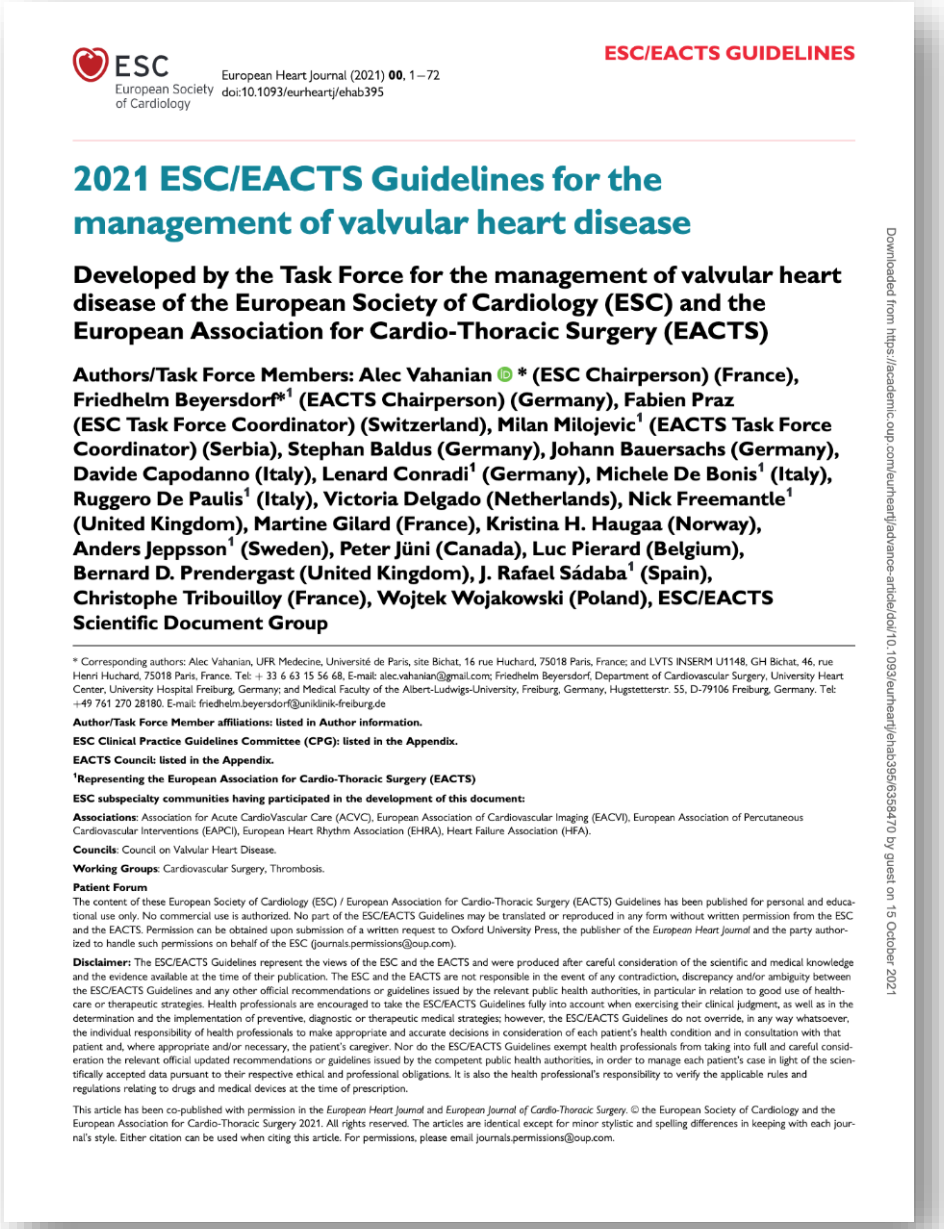
PASCAL

PASCAL PASCAL Ace

Windecker S. et al. JACC Intv. 2021;13(20):2358-60

Клапанная патология

Guidelines по лечению пациентов



ESC European Society of Cardiology

European Heart Journal (2021) **00**, 1–72
doi:10.1093/eurheartj/ehab395

ESC/EACTS GUIDELINES

2021 ESC/EACTS Guidelines for the management of valvular heart disease

Developed by the Task Force for the management of valvular heart disease of the European Society of Cardiology (ESC) and the European Association for Cardio-Thoracic Surgery (EACTS)

Authors/Task Force Members: Alec Vahanian * (ESC Chairperson) (France), Friedhelm Beyersdorf*[1] (EACTS Chairperson) (Germany), Fabien Praz (ESC Task Force Coordinator) (Switzerland), Milan Milojevic[1] (EACTS Task Force Coordinator) (Serbia), Stephan Baldus (Germany), Johann Bauersachs (Germany), Davide Capodanno (Italy), Lenard Conradi[1] (Germany), Michele De Bonis[1] (Italy), Ruggero De Paulis[1] (Italy), Victoria Delgado (Netherlands), Nick Freemantle[1] (United Kingdom), Martine Gilard (France), Kristina H. Haugaa (Norway), Anders Jeppsson[1] (Sweden), Peter Jüni (Canada), Luc Pierard (Belgium), Bernard D. Prendergast (United Kingdom), J. Rafael Sádaba[1] (Spain), Christophe Tribouilloy (France), Wojtek Wojakowski (Poland), ESC/EACTS Scientific Document Group

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Author/Task Force Member affiliations: listed in Author information.

ESC Clinical Practice Guidelines Committee (CPG): listed in the Appendix.

EACTS Council: listed in the Appendix.

[1]Representing the European Association for Cardio-Thoracic Surgery (EACTS)

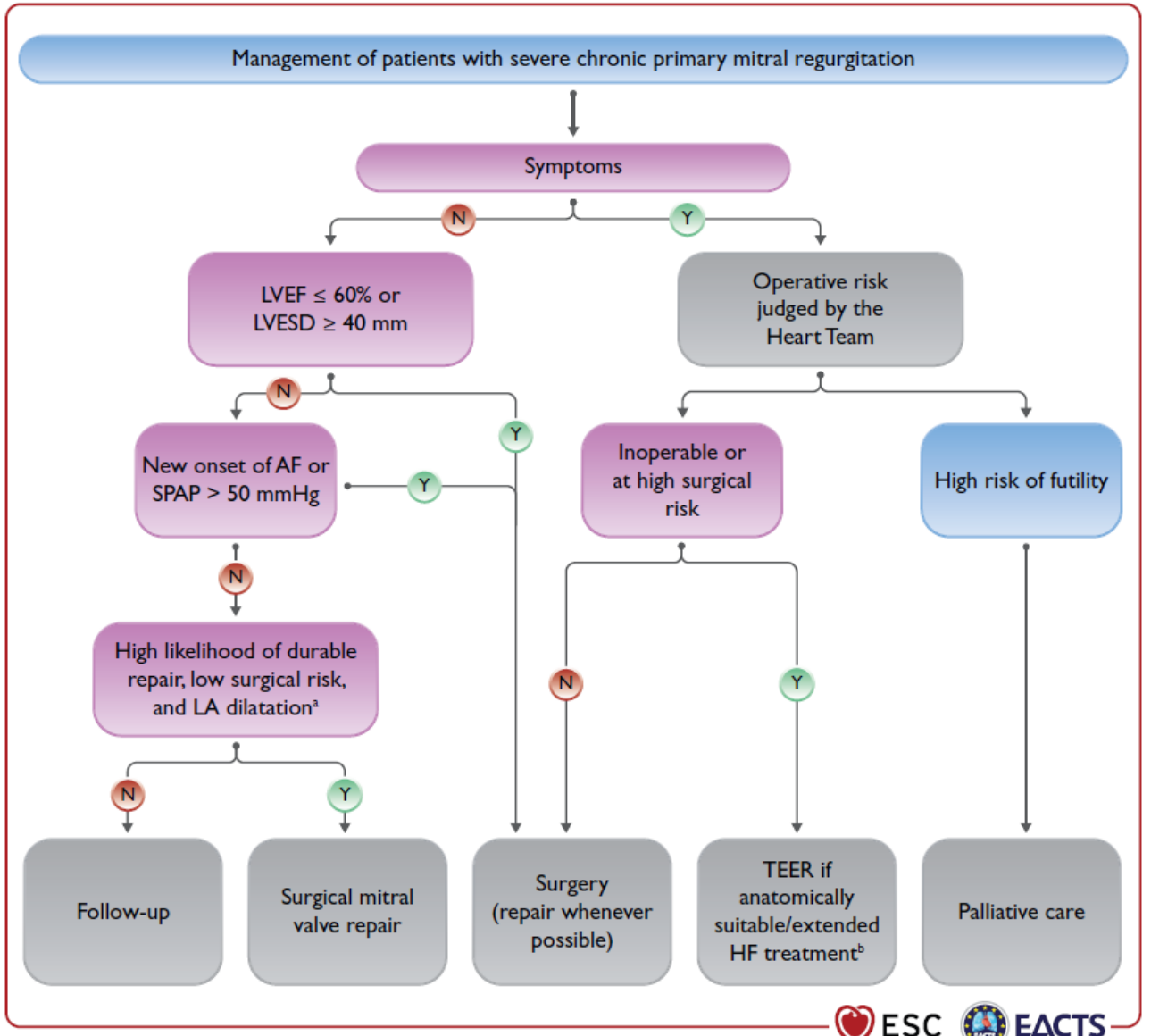
ESC subspecialty communities having participated in the development of this document:

Associations: Association for Acute CardioVascular Care (ACVC), European Association of Cardiovascular Imaging (EACVI), European Association of Percutaneous Cardiovascular Interventions (EAPCI), European Heart Rhythm Association (EHRA), Heart Failure Association (HFA).

Councils: Council on Valvular Heart Disease.

Working Groups: Cardiovascular Surgery, Thrombosis.

Guidelines по лечению пациентов



Guidelines по лечению пациентов с первичной митральной недостаточностью

TEER may be considered in symptomatic patients who fulfil the echocardiographic criteria of eligibility, are judged inoperable or at high surgical risk by the Heart Team and for whom the procedure is not considered futile [299–302].	IIb	B

MITRA Clip процедура показана - неоперабельным пациентам с выраженной клинической симптоматикой, у которых по даным ЭХО возможно выполнить процедуру

Guidelines по лечению пациентов с вторичной митральной недостаточностью

Patients with concomitant coronary artery or other cardiac disease requiring treatment		
Valve surgery is recommended in patients undergoing CABG or other cardiac surgery [329, 330, 333].	**I**	**B**
In symptomatic patients, who are judged not appropriate for surgery by the Heart Team on the basis of their individual characteristics,[d] PCI (and/or TAVI) possibly followed by TEER (in case of persisting severe SMR) should be considered.	**IIa**	**C**

MITRA Clip процедура показана - неоперабельным пациентам после выполнения PCI или TAVI

Guidelines по лечению пациентов с вторичной митральной недостаточностью

Patients without concomitant coronary artery or other cardiac disease requiring treatment		
TEER should be considered in selected symptomatic patients, not eligible for surgery and fulfilling criteria suggesting an increased chance of responding to the treatment [337, 338, 356, 357]. [e]	IIa	B
Valve surgery may be considered in symptomatic patients judged appropriate for surgery by the Heart Team.	IIb	C
In high-risk symptomatic patients not eligible for surgery and not fulfilling the criteria suggesting an increased chance of responding to TEER, the Heart Team may consider in selected cases a TEER procedure or other transcatheter valve therapy if applicable, after careful evaluation for ventricular assist device or heart transplant.[e]	IIb	C

MITRA Clip процедура показана - неоперабельным пациентам у которых по даным ЭХО возможно выполнить эту процедуру с учетом терапии сердечной недосточности

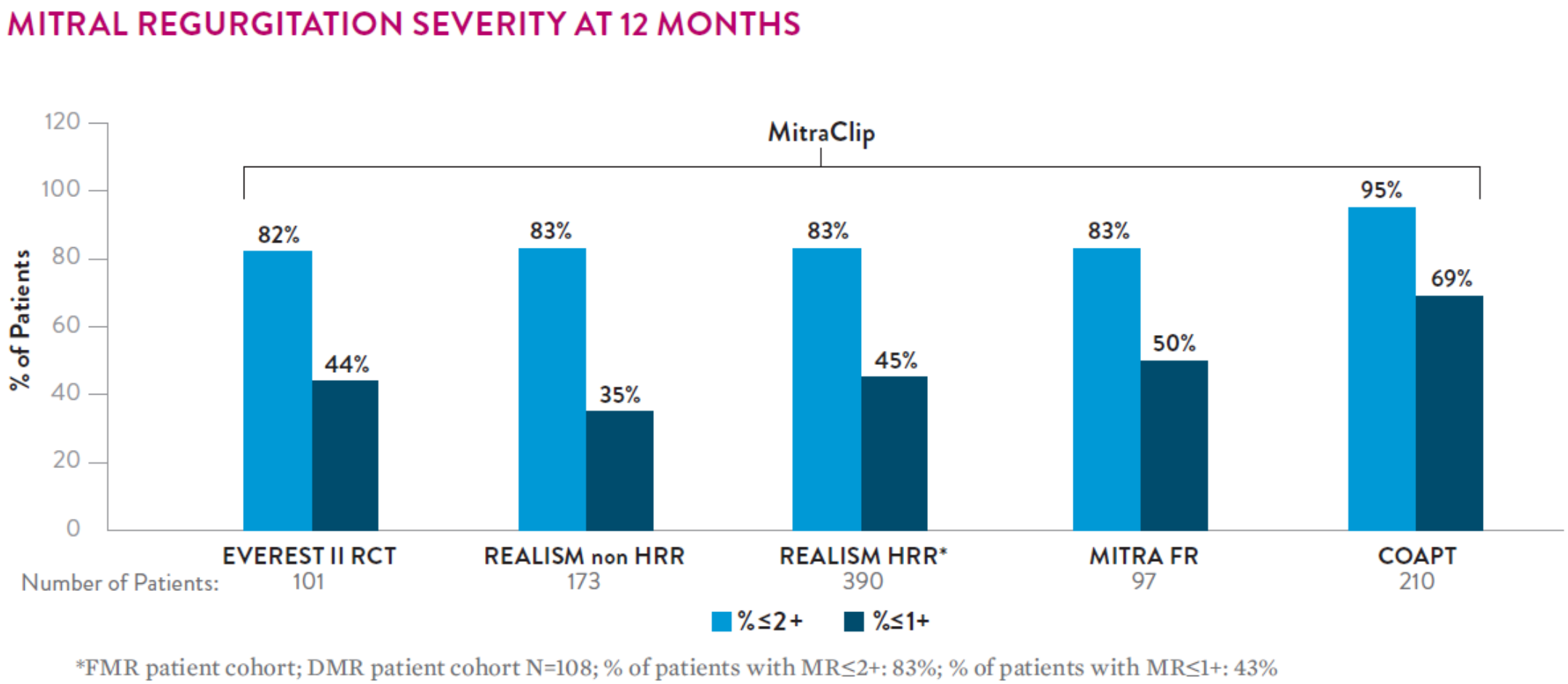
Интервенционное лечение МН

Показания к лечению

- Пожилые пациенты
- Неоперабельные пациенты
- Пациенты с высоким риском
- Повторные операции
- Сопутствующая патология
- Вторичная МН > первичная МН
- Сниженная функция ЛЖ
- Пациенты у которых есть возможность выполнить эту операцию по данным ЭХО

Интервенционное лечение МН

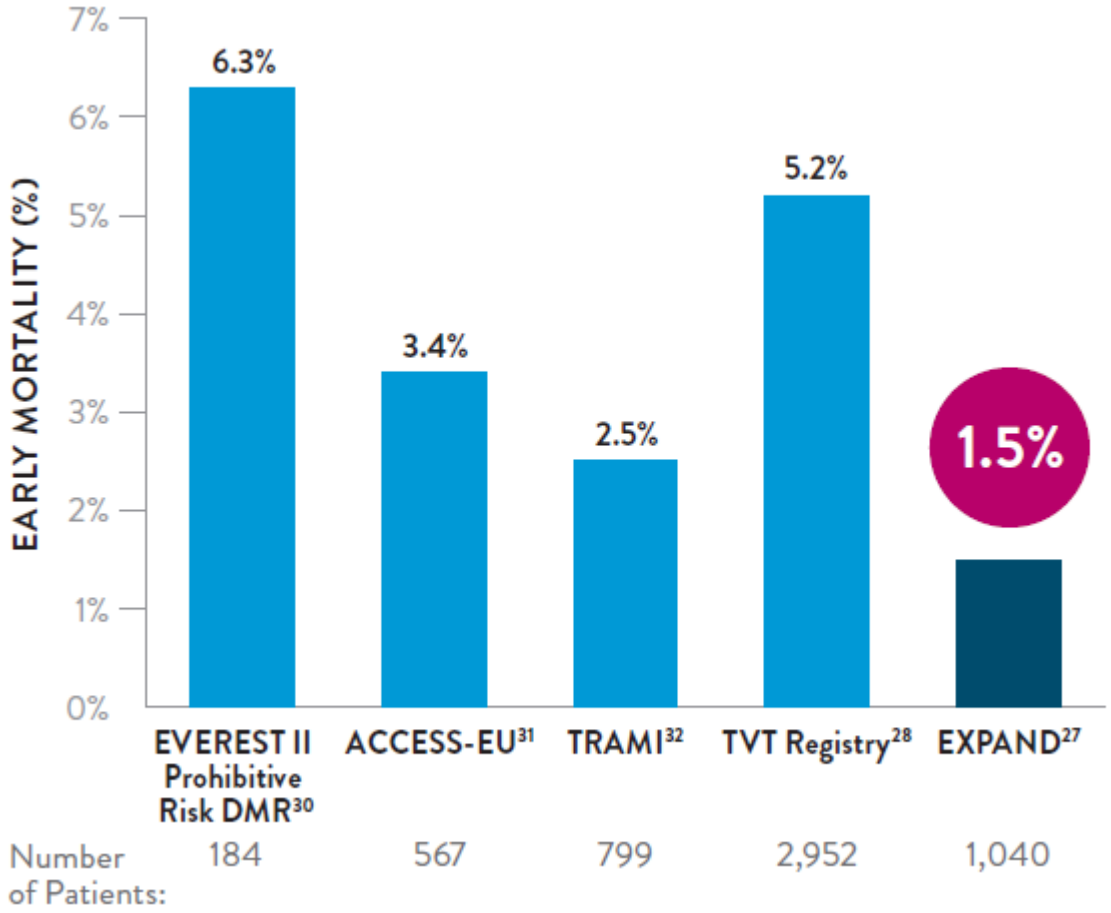
Mitra Clip clinicals trial

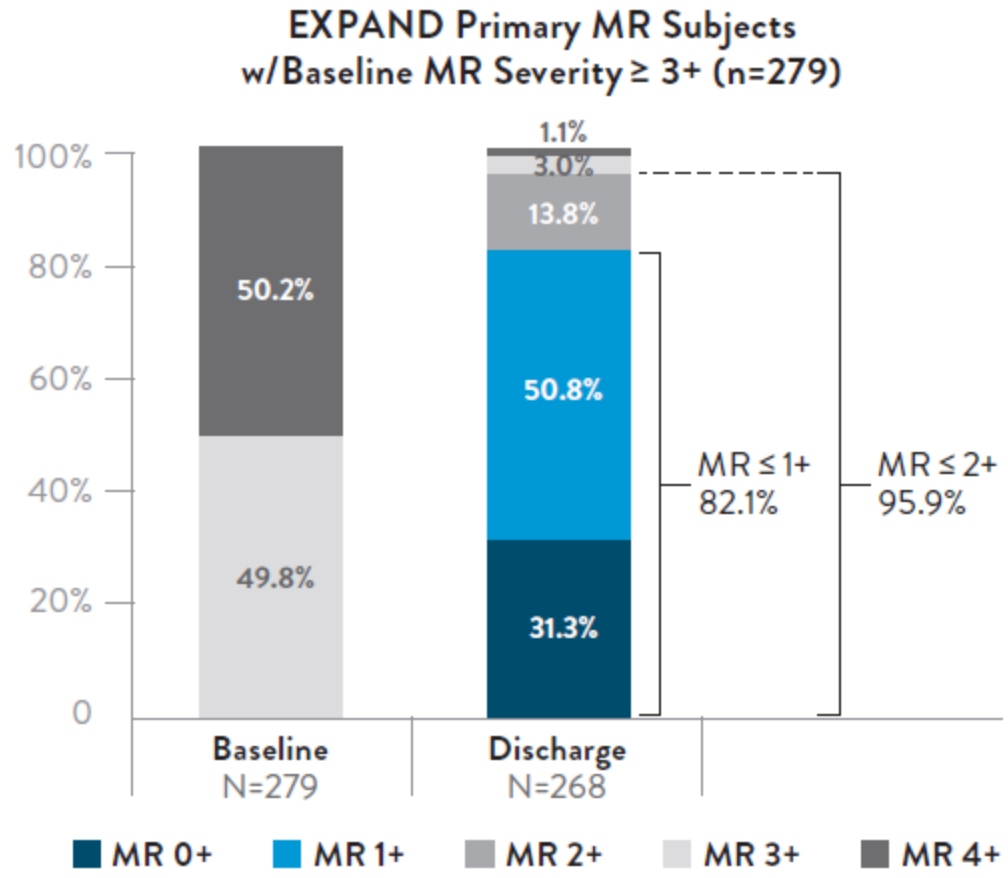


*FMR patient cohort; DMR patient cohort N=108; % of patients with MR≤2+: 83%; % of patients with MR≤1+: 43%

Интервенционное лечение МН

Expand Study





Интервенционное лечение МН

Clasp IID trial

JACC: CARDIOVASCULAR INTERVENTIONS VOL. 15, NO. 24, 2022
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STRUCTURAL

Randomized Comparison of Transcatheter Edge-to-Edge Repair for Degenerative Mitral Regurgitation in Prohibitive Surgical Risk Patients

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ABSTRACT

BACKGROUND Severe symptomatic degenerative mitral regurgitation (DMR) has a poor prognosis in the absence of treatment, and new transcatheter options are emerging.

OBJECTIVES The CLASP IID (Edwards PASCAL Transcatheter Valve Repair System Pivotal Clinical Trial) randomized trial (NCT03706833) is the first to evaluate the safety and effectiveness of the PASCAL system compared with the MitraClip system in patients with significant symptomatic DMR. This report presents the primary safety and effectiveness endpoints for the trial.

METHODS Patients with 3+ or 4+ DMR at prohibitive surgical risk were assessed by a central screening committee and randomized 2:1 (PASCAL:MitraClip). Study oversight also included an echocardiography core laboratory and a clinical events committee. The primary safety endpoint was the composite major adverse event rate at 30 days. The primary effectiveness endpoint was the proportion of patients with mitral regurgitation (MR) ≤2+ at 6 months.

RESULTS A prespecified interim analysis in 180 patients demonstrated noninferiority of the PASCAL system vs the MitraClip system for the primary safety and effectiveness endpoints of major adverse event rate (3.4% vs 4.8%) and MR ≤2+ (96.5% vs 96.8%), respectively. Functional and quality-of-life outcomes significantly improved in both groups ($P < 0.05$). The proportion of patients with MR ≤1+ was durable in the PASCAL group from discharge to 6 months (PASCAL, 87.2% and 83.7% [$P = 0.317$ vs discharge]; MitraClip, 88.5% and 71.2% [$P = 0.003$ vs discharge]).

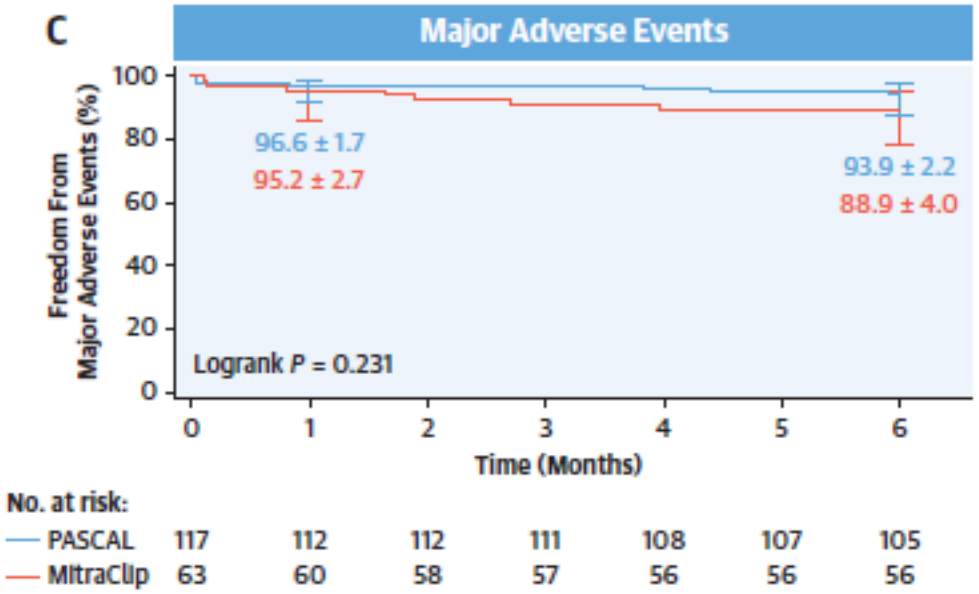
CONCLUSIONS The CLASP IID trial demonstrated safety and effectiveness of the PASCAL system and met noninferiority endpoints, expanding transcatheter treatment options for prohibitive surgical risk patients with significant symptomatic DMR. (J Am Coll Cardiol Intv 2022;15:2523-2536) © 2022 by the American College of Cardiology Foundation.

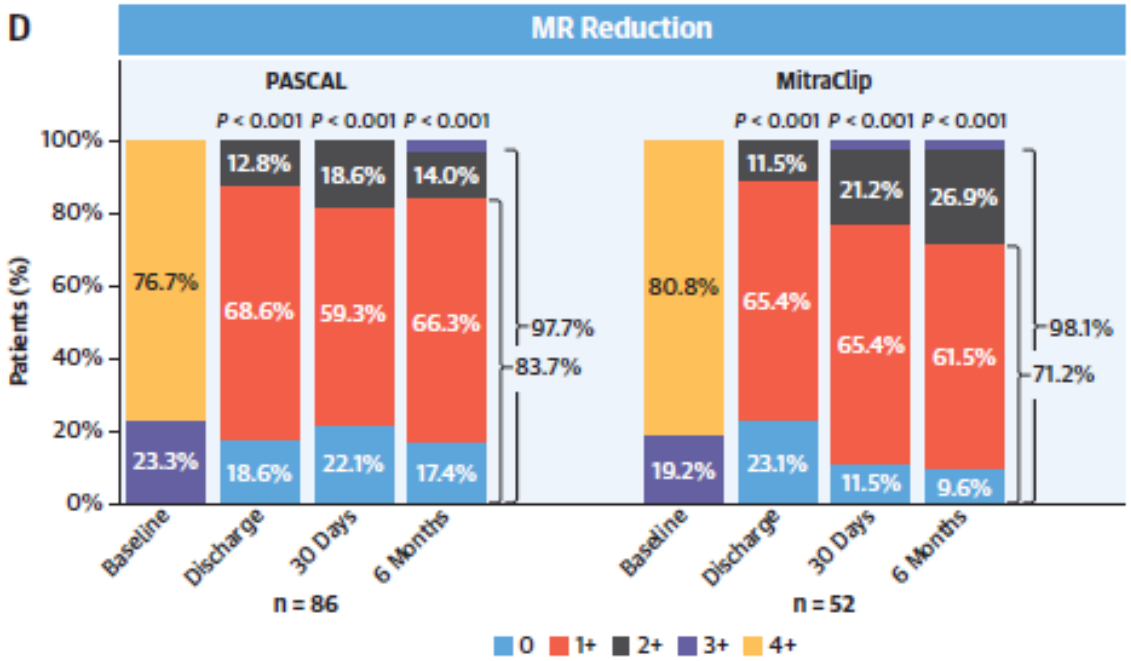
- МН III – IV ст.
- randomized 2:1 (PASCAL : MitraClip)

Lim. et al. JACC 2022

Интервенционное лечение МН

Clasp IID trial

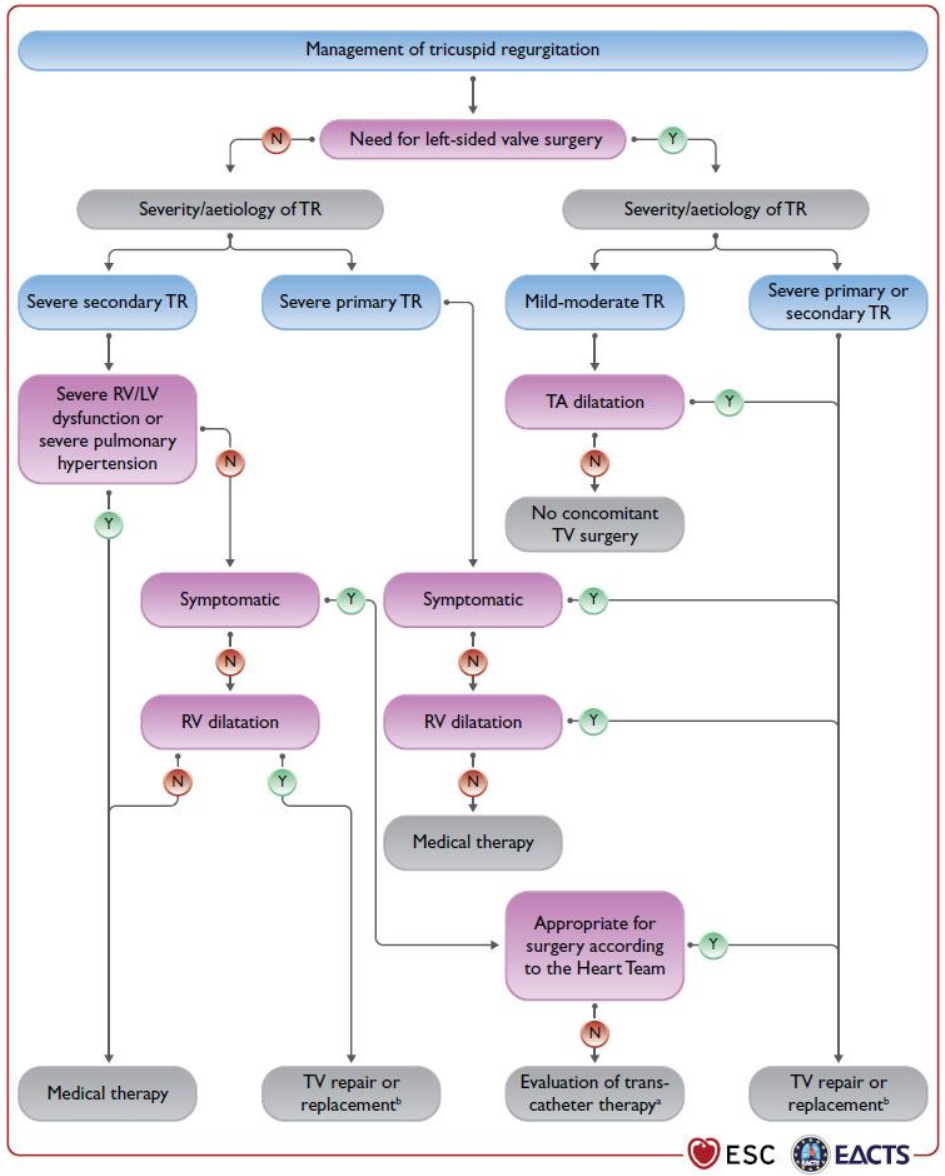




Lim. et al. JACC 2022

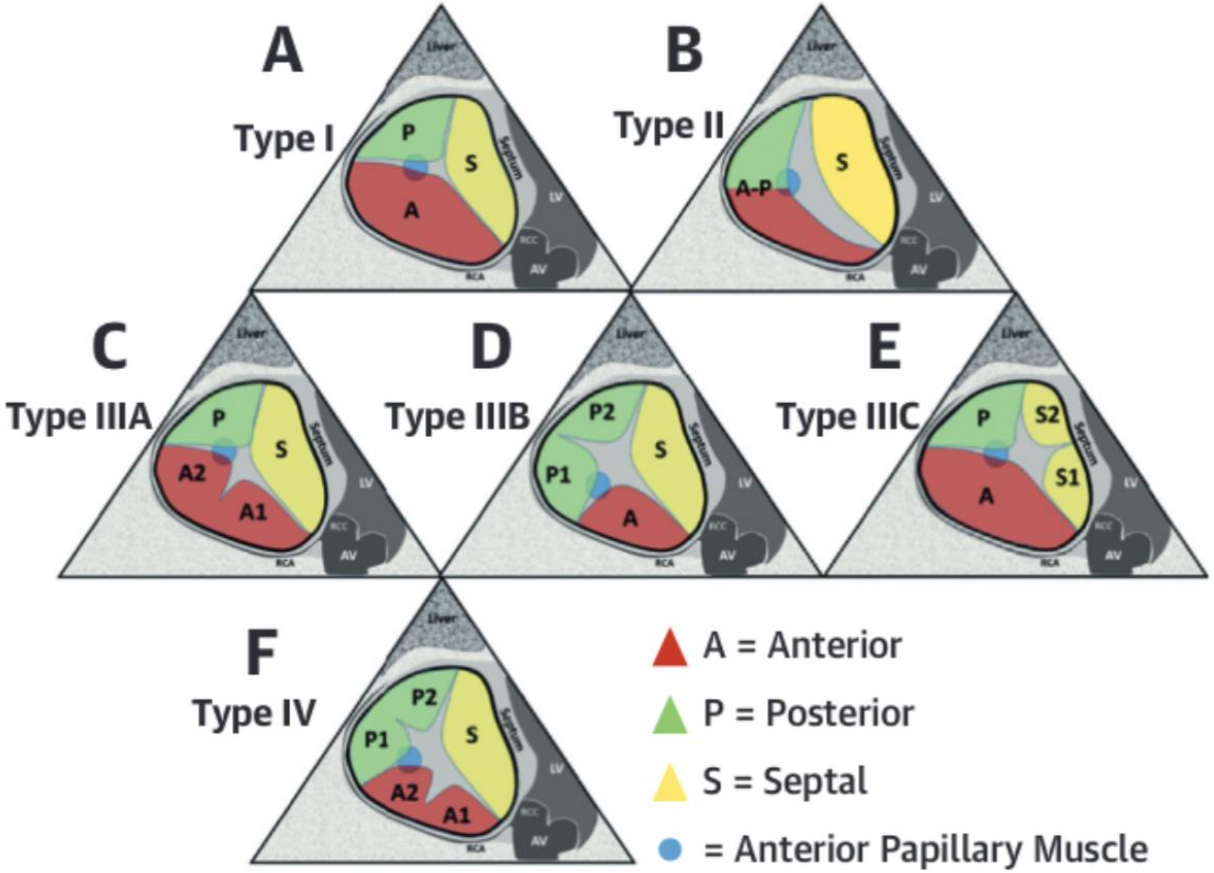
Трикуспидальная недостаточность

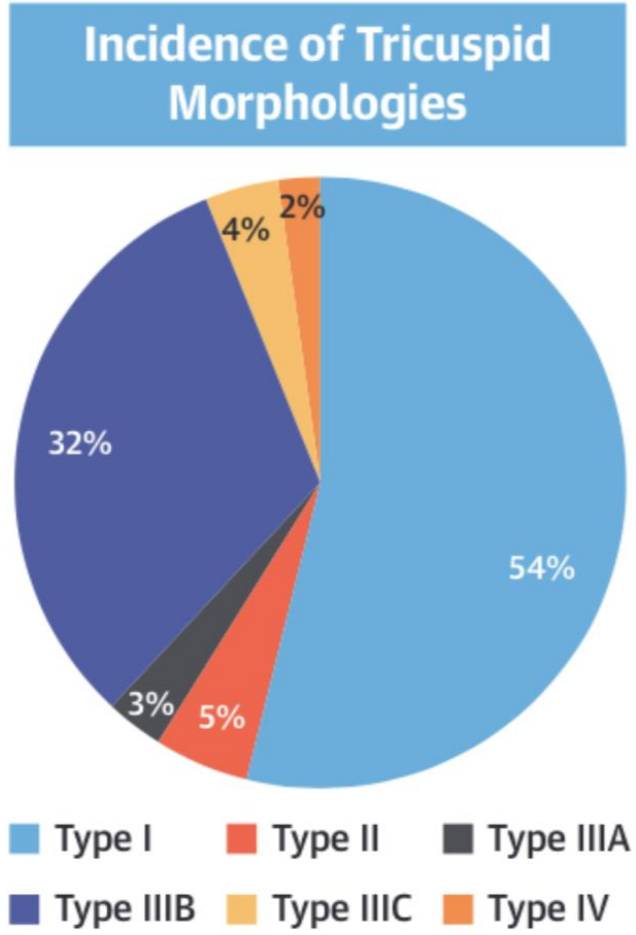
Подходы в лечении тяжелой трикуспидальной недостаточности



Tricuspid Valve Anatomy

Новое понимание





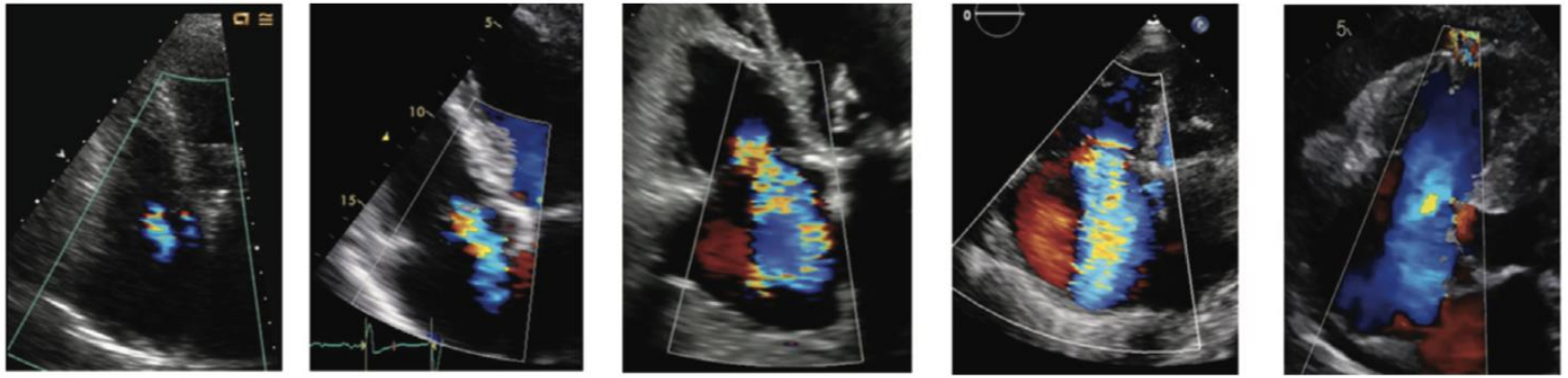
Hahn, R.T. et al. J Am Coll Cardiol Img. 2021;14(7):1299–305

Isolated Tricpspid Regurgitation

Схема оценки

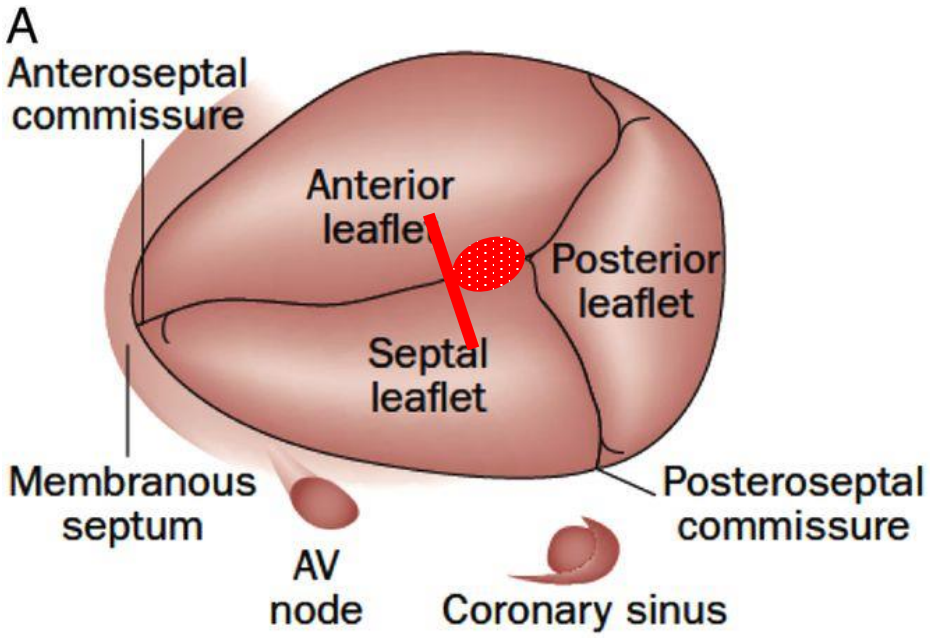
Stage	1 < Moderate	2 ≥ Moderate	3-5 Servere - Torrential		
Parameters	**MILD**	**MODERATE**	**SEVERE**	**MASSIVE**	**TORRENTIAL**
Vena Contracta width (biplane average)	<3 mm	3-6.9 mm	7 mm - 13 mm	14-20 mm	≥21 mm
EROA by PISA	<20 mm^2	20-39 mm^2	40-59 mm^2	60-79 mm^2	≥80 mm^2
3D Vena Contracta Area or Quantitative Doppler EROA	-	-	75-94 mm^2	95-114 mm^2	≥115 mm^2

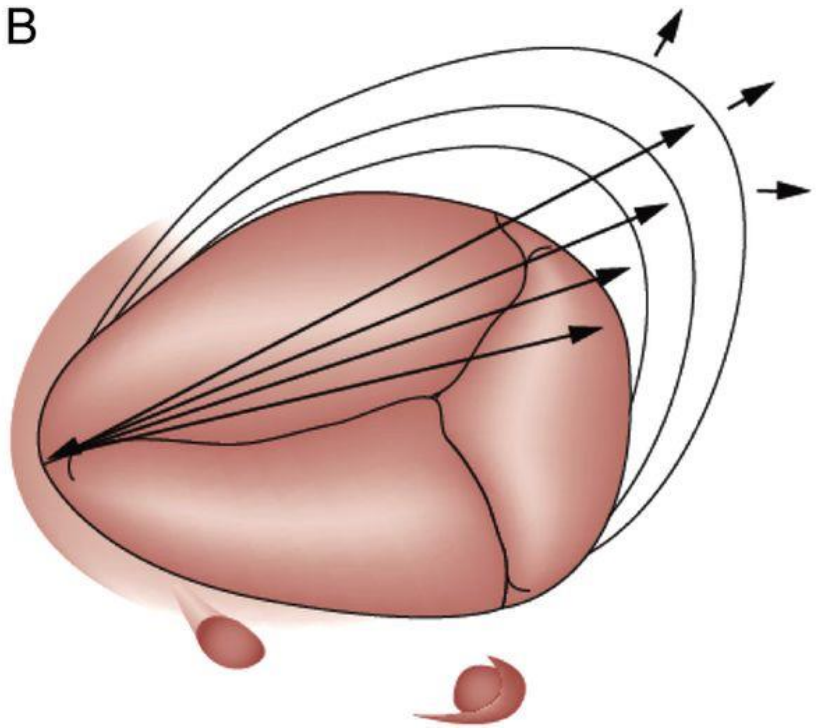
Example:



Hahn, R.T. et al. J Am Coll Cardiol Img. 2019;12(3):469–90

Транскатетерная реконструкция ТК – имплантация TriClip





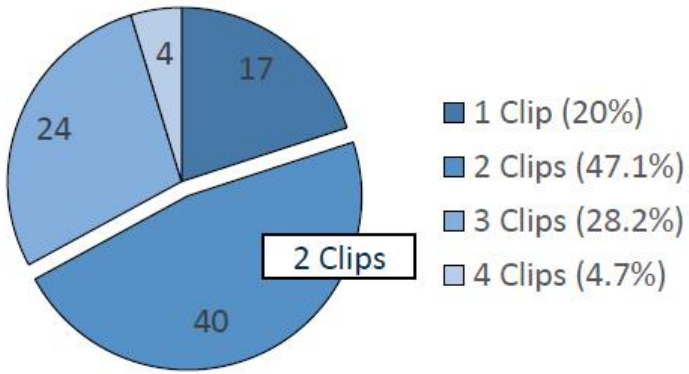
1-2 clip strategy

Arsalan M et al.; Eur Heart J 2015; ePub ahead of print

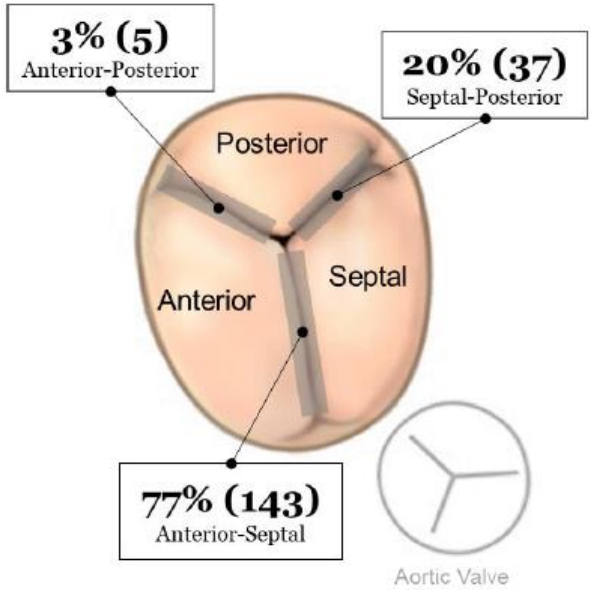
Tri Clip – Triluminate Study

TRILUMINATE | Procedural Data

Number of Clips Implanted per Subject (n=85 subjects)



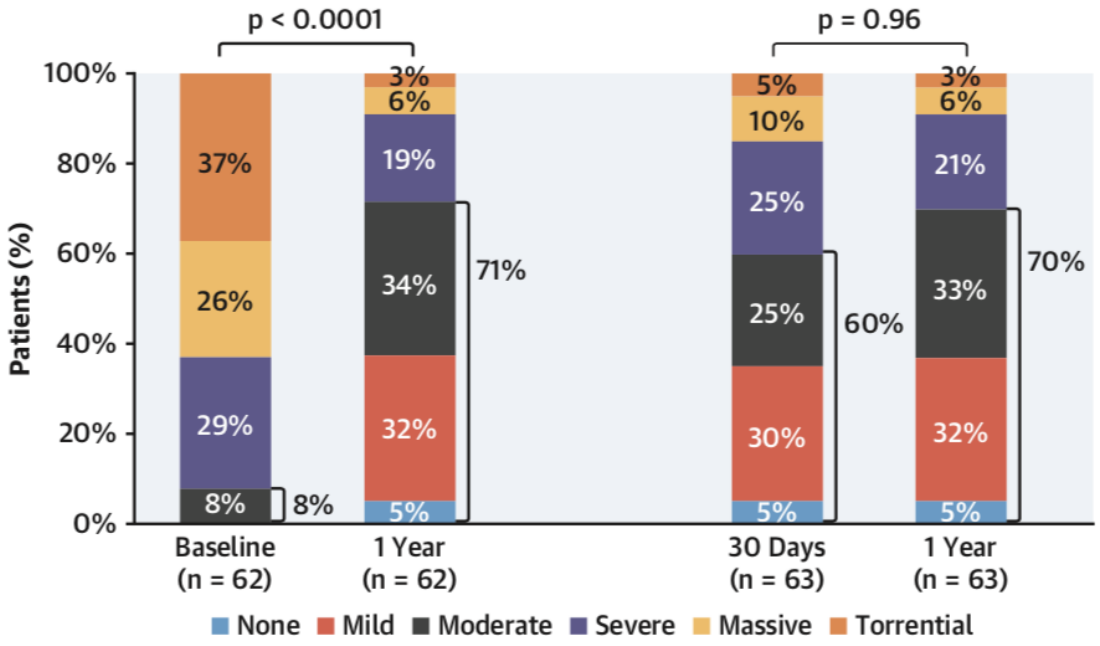
Clipping Location (n=185 Clips)



Lurz, P. et al. J Am Coll Cardiol. 2021;77(3):229-39.
Nickenig, G. et al. The Lancet. 2020;394(10213):2002-2011

Tricuspid Valve Repair

Транскатетерная реконструкция ТК – **TRILUMINATE Trial**



30d mortality = 0.0 %

1y survival = 92.9 %

Lurz, P. et al. J Am Coll Cardiol. 2021;77(3):229-39.
Nickenig, G. et al. The Lancet. 2020;394(10213):2002-2011

Summary

- Эндоваскулярное лечение патологии митрального и трикуспидального клапана показано пациентам высокого риска
- «Edge-to-edge» техника позовляет достоверно снизить степень митральной и трикуспидальной недостаточности
- «Edge-to-edge» техника - стабильные отдаленные результаты
- Предоперационая диагностика – один из решающих факторов в опередлении тактики лечения

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