Como Podemos Hacer MitraClip en Argentina ?

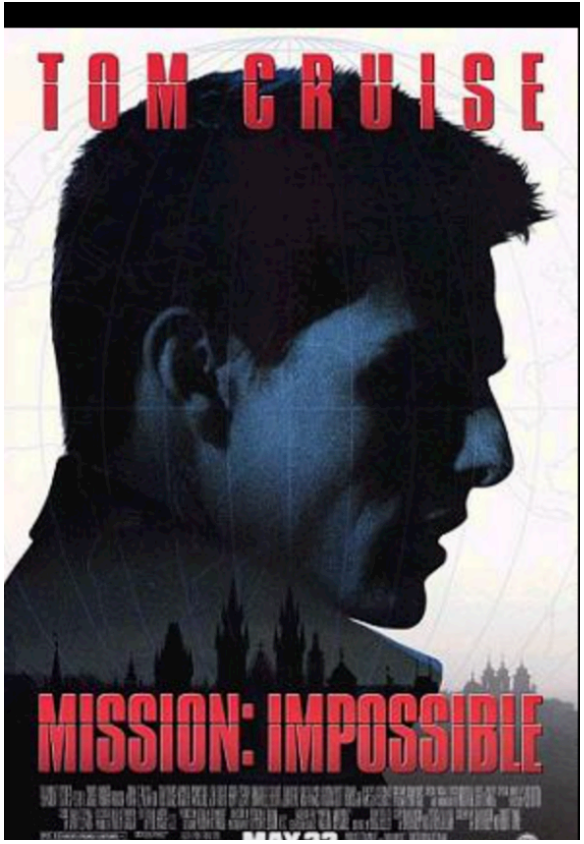
Oscar A. Mendiz.MD.FACC.FSCAI
Director Cardiology & Cardiovascular Institute (ICyCC)
Chief Interventional Cardiology Department
Board of Directors Hospital & Favaloro University

Conflictos de Interés

O Mendiz MD.

Medtronic: Proctor CoreValve, Speaker, Hospital Agreement
Abbott: Hospital Agreement
Boston Scientific: Consultant
Phillips: Consultant, Hospital Agreement
Jotec-Oclutech: Sposes

Como Podemos Hacer MitraClip en Argentina?




IMPOSSIBLE
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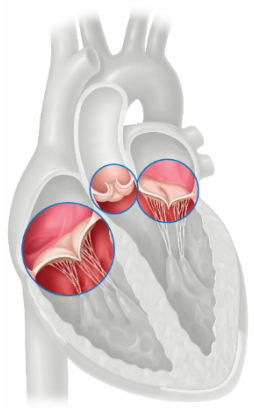
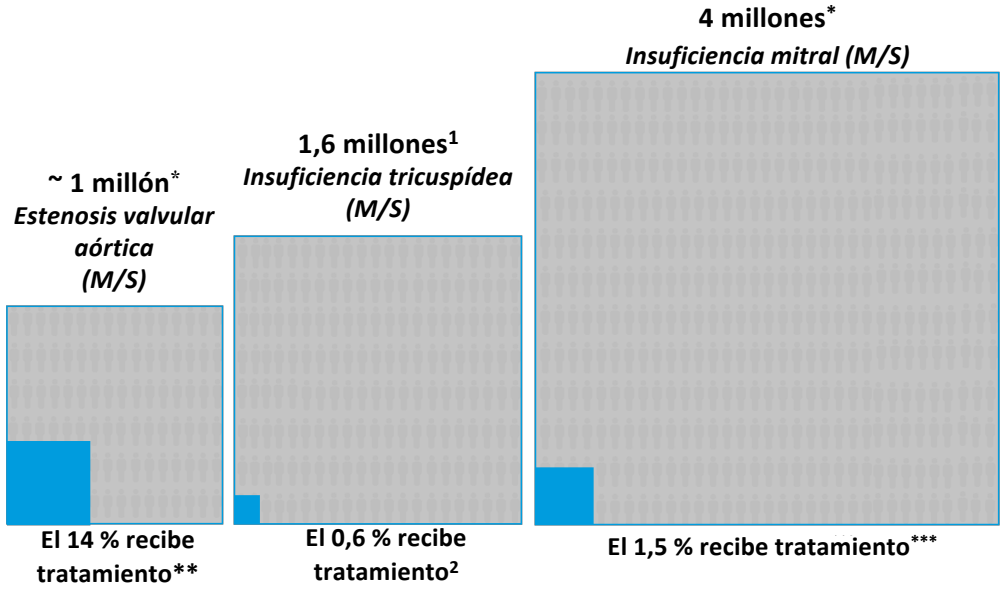
Insuficiencia Mitral:

Magnitud del Problema

LA INSUFICIENCIA MITRAL (IM) COMPROMETE MÁS VIDAS QUE CUALQUIER OTRA ENFERMEDAD DE LA VÁLVULA

PREVALENCIA DE LA ENFERMEDAD EN EE. UU.





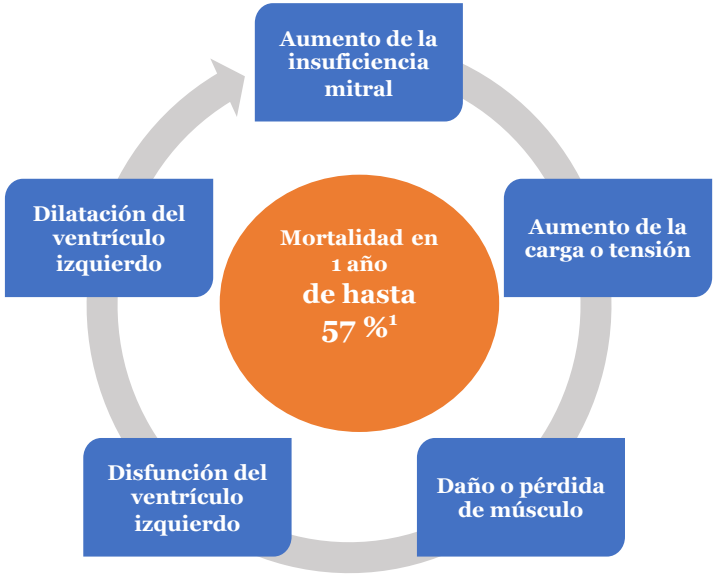
1. Stuge O, Liddicoat J. Emerging opportunities for cardiac surgeons within structural heart disease. J Thorac Cardiovasc Surg. 2006; 132 (6) p.1258-1261, Table 2.
2.. Millennium Research Group. US Markets for Heart Valve Devices 2014. 2013; RPUS12HV13:151

*Cálculos basados en los datos de las referencias 2 y 3.

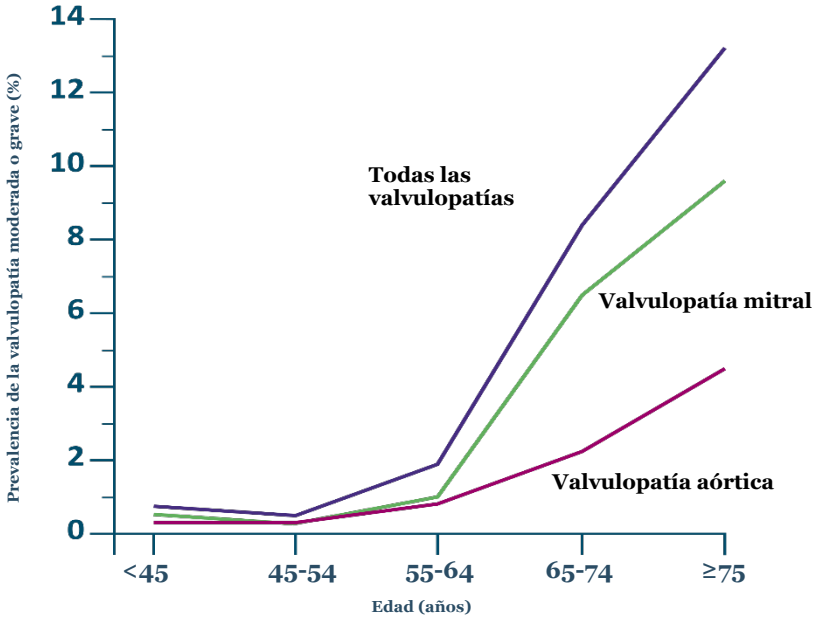
**Cálculo basado en los datos de Mills J, Furlong C. CANACCORD: Biomedical Devices and Services. Nov 8, 2016 and Millennium Research Group. US Markets for Heart Valve Devices 2014. 2013; RPUS12HV13:92. ***Datos en los archivos de Abbott.

LA INSUFICIENCIA MITRAL ES UNA ENFERMEDAD PROGRESIVA

Si no se trata adecuadamente, la IM puede derivar en una insuficiencia cardíaca y ocasionar la muerte[1-3]



LA VALVULOPATÍA MITRAL ES 2 A 3 VECES MÁS FRECUENTE QUE LA VALVULOPATÍA AÓRTICA



1. Cioffi G, et al. Functional mitral regurgitation predicts 1-year mortality in elderly patients with systolic chronic heart failure. European Journal of Heart Failure 2005 Dec;7(7):1112-7. 2. Enriquez-Sarano M, Avierinos JF, Messika-Zeitoun D, et al. Quantitative determinants of the outcome of asymptomatic mitral regurgitation.N Engl J Med. 2005;352(9):875-883. 3. Grigioni F, Tribouilloy C, Avierinos JF, et al; MIDA Investigators. Outcomes in mitral regurgitation due to flail leaflets: a multicenter European study. JACC Cardiovasc Imaging. 2008;1(2):133-141.

Nkomo, et al. Lancet. 2006; 368: 1007

NECESIDAD CLÍNICA INSATISFECHA

IM aislada (n = 877)

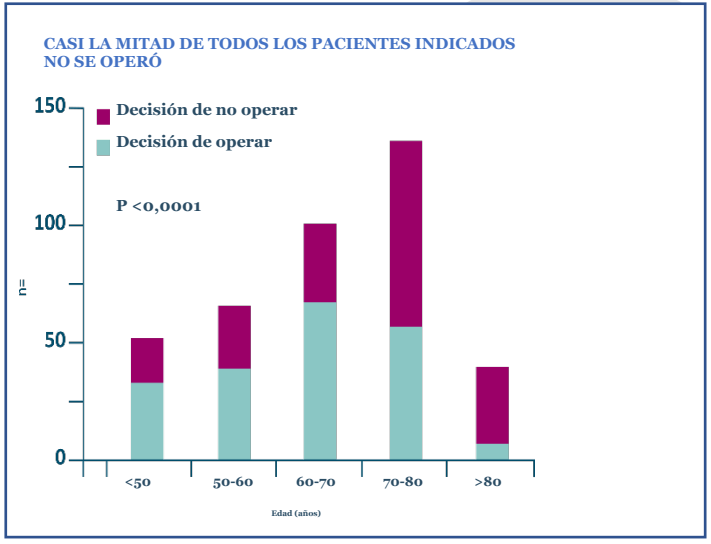
IM severa (n = 546)

Sin síntomas (n = 144)

Síntomas (n = 396)

Ninguna intervención (n = 193; 49 %)

Intervención (n = 203; 51 %)



Mirabel M, et al. Eur Heart J 2007;28:1358-1365


European Heart Journal (2007) 28, 1358–1365
doi:10.1093/eurheartj/ehm001

Clinical research
Valvular heart disease

What are the characteristics of patients with severe, symptomatic, mitral regurgitation who are denied surgery?

Mariana Mirabel[1], Bernard Iung[1]*, Gabriel Baron[2], David Messika-Zeitoun[1], Delphine Détaint[1], Jean-Louis Vanoverschelde[3], Eric G. Butchart[4], Philippe Ravaud[2], and Alec Vahanian[1]

[1]Cardiology Department, Bichat Hospital, AP-HP, 46 rue Henri Huchard, 75018 Paris, France; [2]Épidemiology, Biostatistic, and Clinical Research Department, Bichat Hospital, AP-HP, Paris, France; [3]Cliniques Universitaires Saint-Luc, Brussels, Belgium; and [4]Cardiac Surgery Department, University Hospital, Cardiff, Wales, UK

Received 17 July 2006; revised 5 February 2007; accepted 9 February 2007; online publish-ahead-of-print 9 March 2007

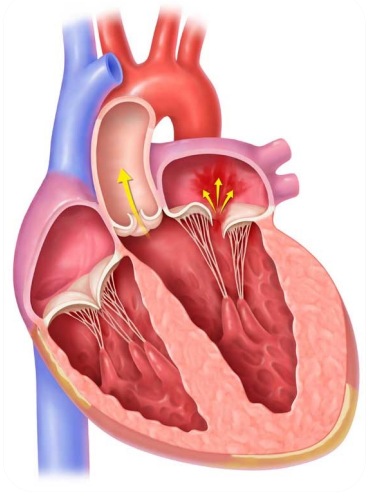
See page 1281 for the editorial comment on this article (doi:10.1093/eurheartj/ehm156)

KEYWORDS
Mitral regurgitation;
Mitral valve replacement;
Mitral valve repair;
Decision-making

Aim To identify the proportion and characteristics of patients with severe symptomatic mitral regurgitation (MR) who are denied surgery.
Methods and results In the Euro Heart Survey on valvular heart disease, 396 patients had severe symptomatic MR as assessed by Doppler-echocardiography (grade ≥ 3+) and New York Heart Association class II or greater. Patient characteristics were analysed according to the decision to operate or not.

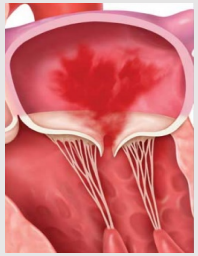
Clasificación de IM: 2 tipos

La IM se produce cuando la válvula mitral no se cierra completamente, lo que hace que el flujo sanguíneo regrese a la aurícula izquierda[1]



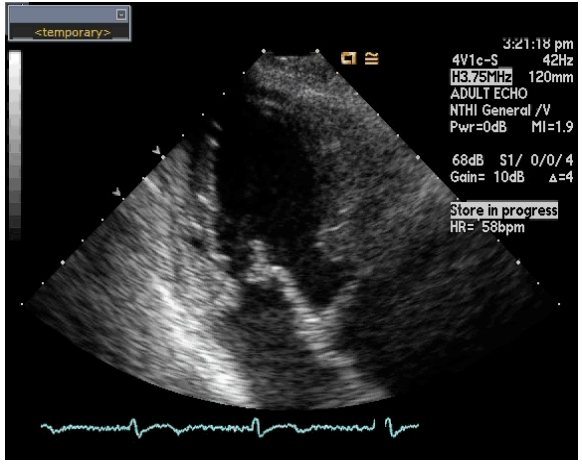
ANOMALÍA DE LA VÁLVULA DEGENERATIVA

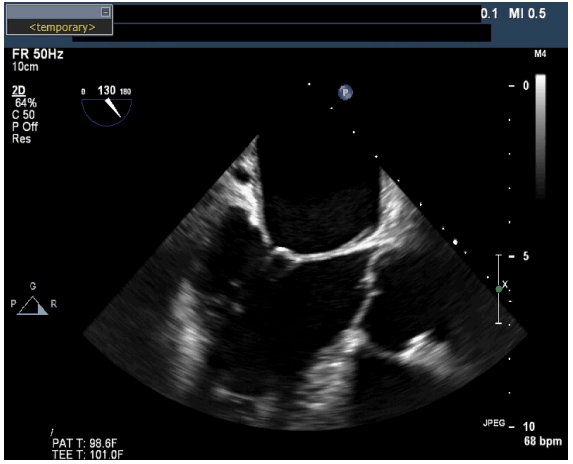
- Valvas
- Aparato subvalvular
- Cuerdas y músculos papilares



DILATACIÓN DEL VENTRÍCULO IZQUIERDO FUNCIONAL

- Restricción de la valva
- Dilatación del anillo mitral
- Coaptación incompleta de la válvula mitral

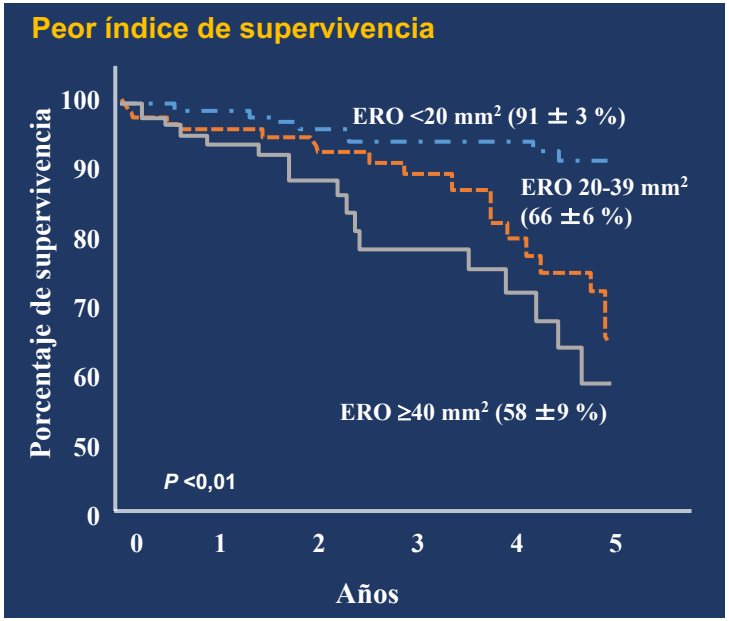




1. Mayo Clinic Staff. Mitral valve regurgitation: symptoms and causes. The Mayo Clinic. http://www.mayoclinic.org/diseases-conditions/mitral-valve-regurgitation/symptoms-causes/dxc-20121850. Publicado el 22 marzo de 2016. Consultado el jueves 28 de julio de 2016.

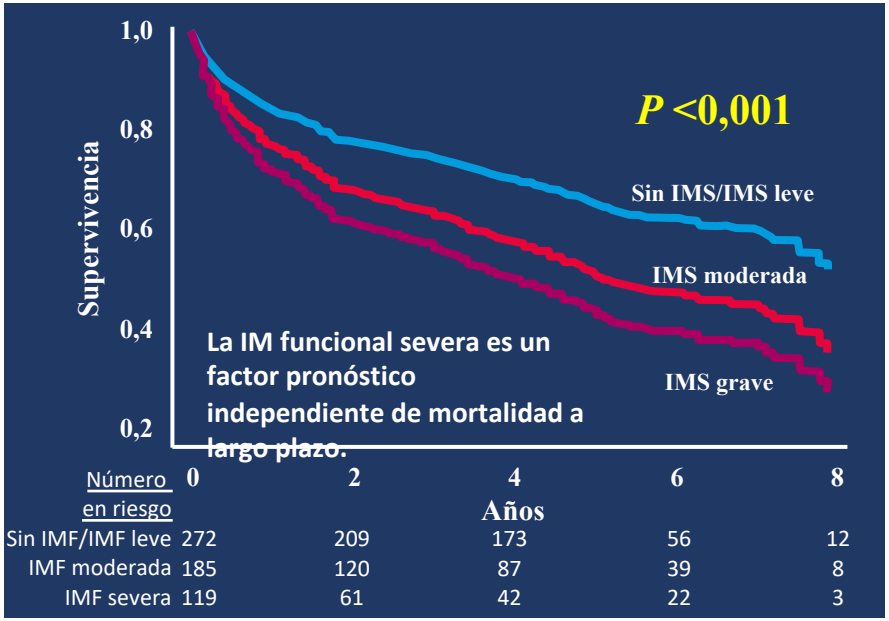
IM: la gravedad afecta la supervivencia

IM DEGENERATIVO



IM FUNCIONAL

Estudio prospectivo: 576 pacientes con ICFEr; 21 % con IMF y 32 % con IMF moderada.

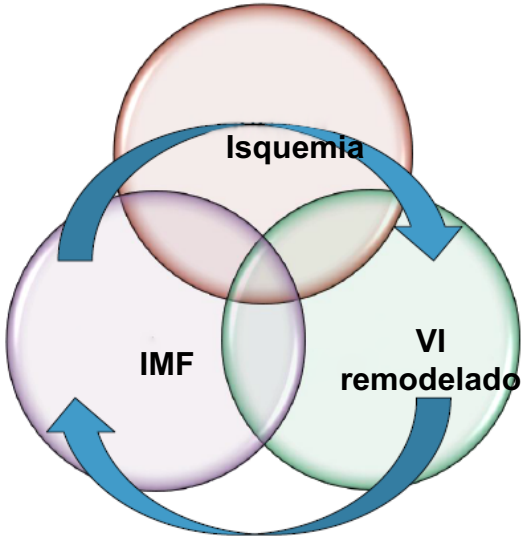


Enriquez-Sarano M et al. NEJM 2005;352:875-83

Goliasch G et al. *EHJ* 2018;39:39-46

Insuficiencia cardíaca e IM funcional

COMORBILIDADES DE LA INSUFICIENCIA CARDÍACA



Isquemia: miocardio aturdido o en hibernación

Fibrosis

Dilatación - remodelado

IM funcional

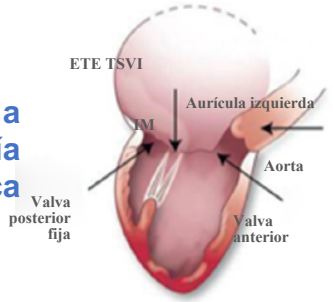
Fibrilación auricular

Disincronía del ventrículo izquierdo

Arritmias malignas

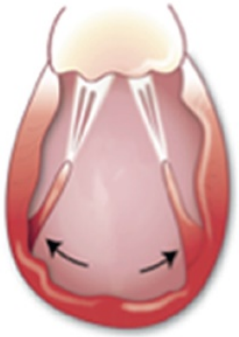
Trastorno neurohumoral

IM debido a miocardiopatía isquémica



MÚSCULO CARDÍACO VENTRICULAR DÉBIL

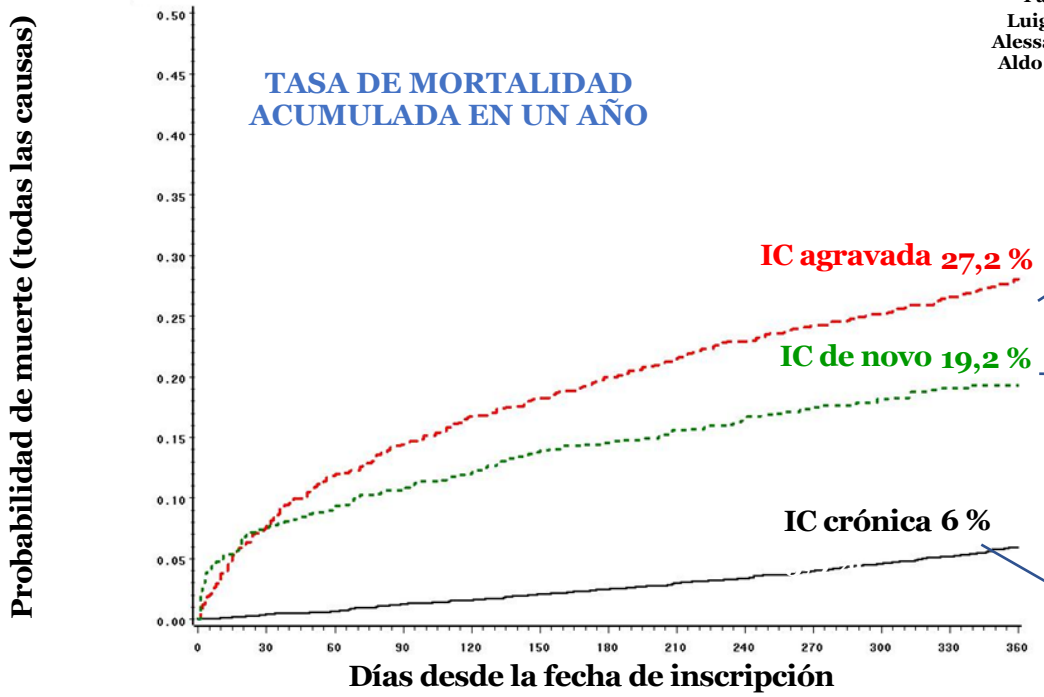
IM como consecuencia de miocardiopatía dilatada idiopática



Fuente: Maisano PCR 2019

Probabilidad de muerte en pacientes con insuficiencia cardíaca: Registro de IN-IC

Multicenter Prospective Observational Study on Acute and Chronic Heart Failure: The One-Year Follow-Up Results of IN-HF Outcome Registry
Luigi Tavazzi, Michele Senni, Metra, Marco Gorini, Giuseppe Cacciatore, Alessandra Chinaglia, Andrea Di Lenarda, Andrea Mortara, Fabrizio Oliva y Aldo P. Maggioni *Circ Heart Fail* publicado en línea el 8 de marzo de 2013;



Aguda = tratada con terapia IV (diuréticos, vasodilatadores, inotrópicos)

Pacientes con insuficiencia cardíaca aguda con antecedentes de IC (N = 1058)

Pacientes con insuficiencia cardíaca aguda sin antecedentes de IC (N = 797)

Pacientes con antecedentes de IC, sin manifestación aguda (N = 3755)

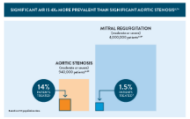
Fuente: Tavazzi L et al. Circ HF March 2013

Tratamiento de la IM y la insuficiencia cardíaca del paciente durante el continuo de la atención

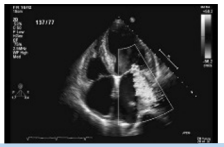
VÍA DEL PACIENTE

Concientización de la enfermedad y educación

Educación del médico y del paciente

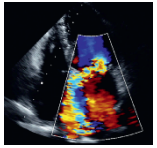


- Programas y herramientas para la educación y concientización



Diagnóstico y vía del paciente

Diagnóstico de IM y permitir que el paciente acceda los tratamiento



- Apoyo de imágenes avanzadas

Opciones de terapia

Intervención temprana antes de la progresión de la IC

- Caja de herramientas para terapia
  - Reparación de VMT
  - **Reemplazo de VMT**
  - TRC

Monitoreo del paciente

Monitoreo para evitar hospitalizaciones por IC

- Monitoreo de la presión arterial pulmonar para prevenir la readmisión

Tratamiento a largo plazo

Opciones de reintervención y terapias avanzadas de IC

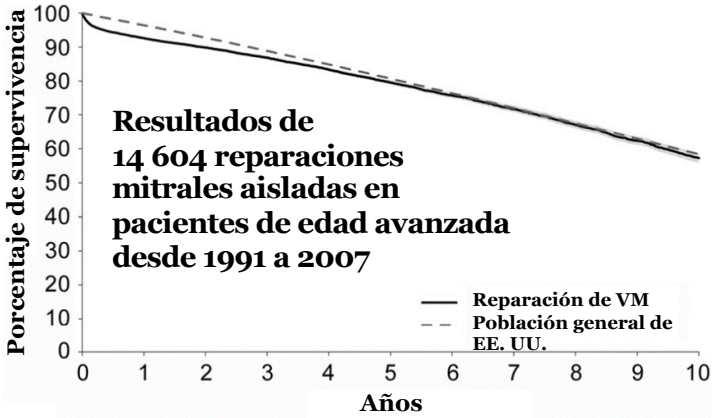
- Reemplazo de VCT
- DAVI

MitraClip:

Indicaciones en las Guías

Insuficiencia mitral primaria: Cambio en las opciones de tratamiento

LA REPARACIÓN QUIRÚRGICA ES EL TRATAMIENTO ESTÁNDAR PARA LOS PACIENTES QUE PUEDEN TOLERAR LA CIRUGÍA



La supervivencia de 10 años tras la reparación de la IM (línea sólida) es equivalente a la población estadounidense agrupada por edad y sexo (línea discontinua) en los pacientes que se someten a reparación primaria aislada de la válvula mitral.

Badhwar et al, Ann Thorac Surg 2012

LA REPARACIÓN PERCUTÁNEA DE BORDE A BORDE SE RECOMIENDA EN PACIENTES CON UN ELEVADO RIESGO QUIRÚRGICO

CDR	NDE	Directrices de tratamiento de IM Degenerativa SEC 2017
IIb	C	El procedimiento **percutáneo de borde a borde** puede considerarse en pacientes con **insuficiencia mitral degenerativa sintomática grave** que cumplan los criterios de elegibilidad ecocardiográficos y sean calificados como **no operables o presenten un elevado riesgo quirúrgico** por el Equipo de Atención Cardiológica, lo que evita la futilidad.

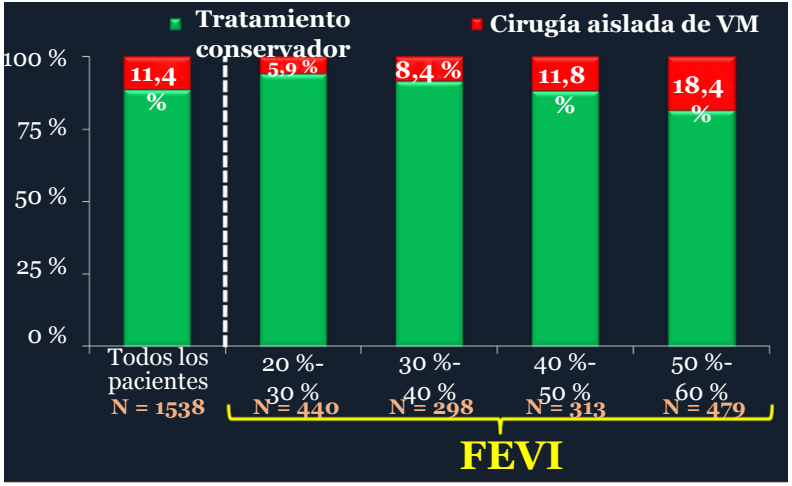
Baumgartner H, Falk V, Bax JJ, et al. Eur Heart J. 2017;00:1-53

CDR	NDE	Directrices de tratamiento de IM Degenerativa ACC/AHA 2014/17
IIb	B	La **reparación de la válvula mitral transcatéter** se puede considerar para pacientes sintomáticos graves (clase III a IV de la NYHA) con **IM degerativa crónica severa (etapa D)** que tengan una anatomía favorable para el procedimiento de reparación y una esperanza de vida razonable, pero tengan un **riesgo quirúrgico prohibitivo** debido a graves comorbilidades, y se trate de pacientes **con síntomas graves, a pesar de una GDMT óptima para el tratamiento de la insuficiencia cardíaca (IC)**.

Tratamiento de IM FUNCIONAL hoy

La terapia médica con o sin RCT es el tratamiento estándar

BASE DE DATOS DUKE: 1538 PACIENTES CON IM SEVERA Y FEVI ≥20 % ENTRE 2000 y 2010 NO SOMETIDOS A IDAC



Fuente: Krucoff, TCT 2014

CDR	NDE	Directrices para la insuficiencia cardíaca de ACC/AHA 2013[1]
I	A	La GDMT debe ser el pilar del tratamiento farmacológico para ICFEr.

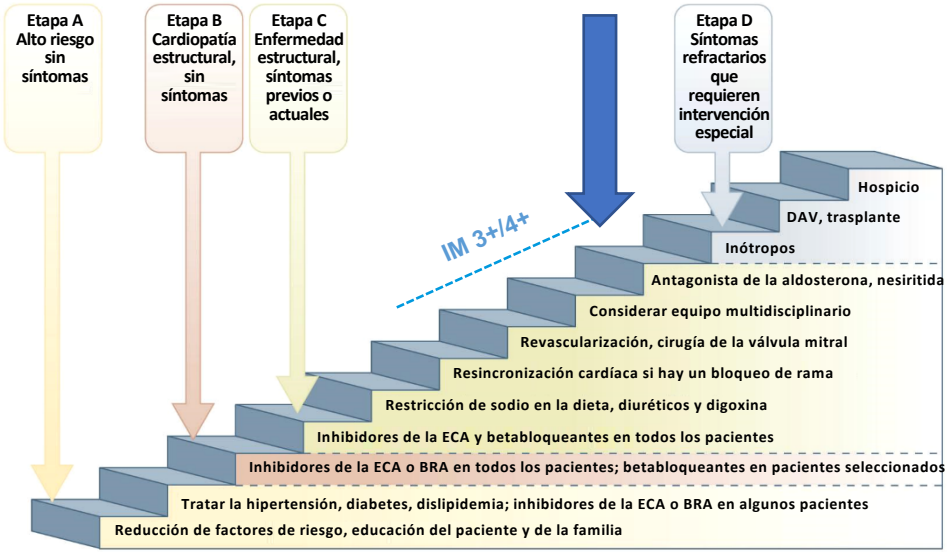
CDR	NDE	Directrices para la insuficiencia cardíaca de SEC 2016[2]
I	C	La terapia médica basada en la evidencia en pacientes con ICFEr se recomienda a fin de reducir la insuficiencia mitral funcional[3].

CDR	NDE	Directrices para la IM valvular Funcional de ACC/AHA 2014/17[3]
I	A	Los pacientes con IM crónica funcional (etapas B a D) e IC con FEVI reducida deben recibir **terapia estándar GDMT para IC**.....
I	A	Se recomienda una **terapia de resincronización cardíaca** con electroestimulación biventricular para pacientes sintomáticos con IM funcional crónica (etapas B a D) grave que cumplan los requisitos para recibir terapia con el dispositivo.

[1] Yancy CW et al. 2013 ACCF/AHA HF Guideline. JACC 62 (16):1495-539. Lo mismo en 2017
[2] Ponikowski P et al., 2016 ESC Heart Failure Guidelines. EHJ 37:2129-2200
[3] Baumgartner H et al., 2017 ESC/EACTS Valve Guidelines. EHJ 00; 1-53

El Tratamiento Basado en las Guías incluye tratamiento no farmacológico, trat. farmacológico (médico) e intervenciones del dispositivo

OBJETIVOS DEL TRATAMIENTO	TIPOS DE INTERVENCIÓN
Reducción del volumen sanguíneo central	Diuréticos
Mejora en la relajación del VI	Bloqueantes de canales de calcio Inhibidores de ECA
Regresión de hipertrofia del VI: disminución en el grosor de la pared y exceso de colágeno	Inhibidores de ECA Antagonistas de la angiotensina Espironolactona
Mantenimiento de la contracción auricular y el control de la frecuencia cardíaca	Betabloqueantes Medicamentos antiarrítmicos TRC



Jessup M, Brozena S. Medical Progress--Heart Failure. N Eng J Med 2003; 348: 2007-2018

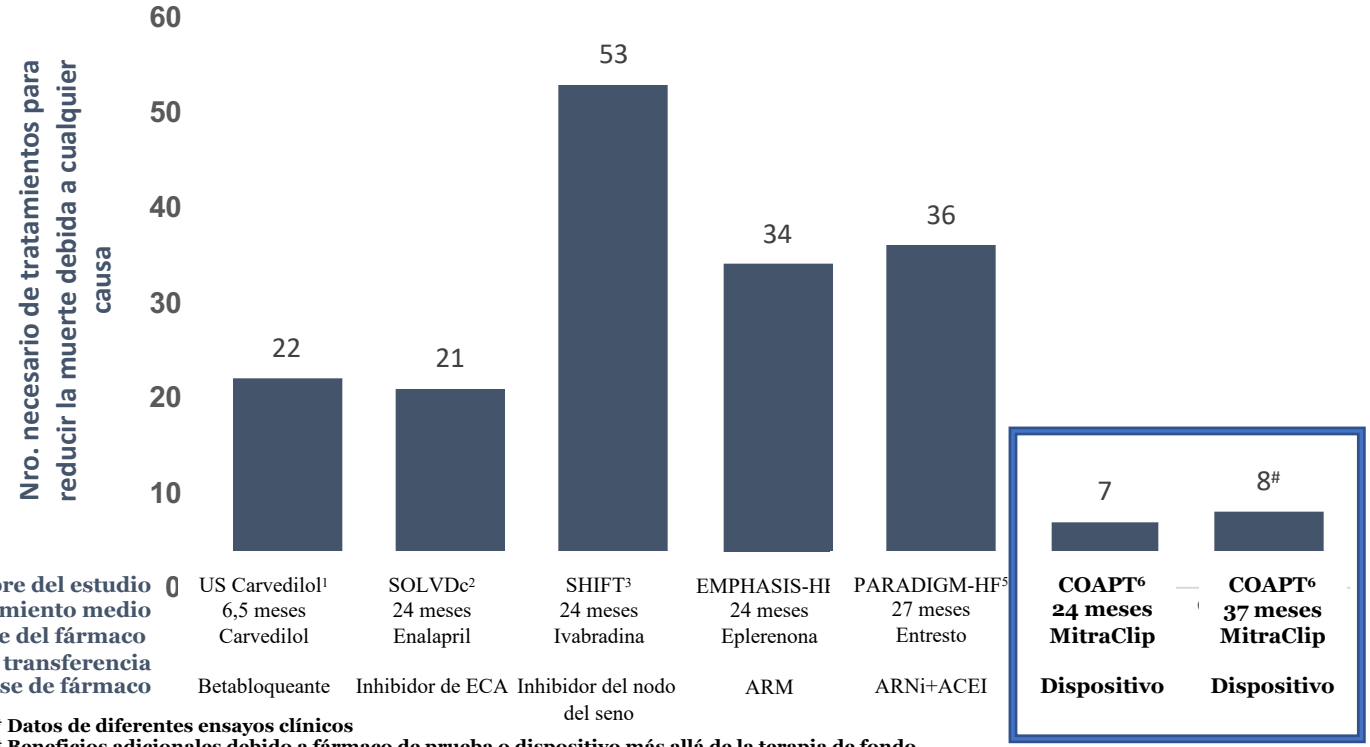
Uso del dispositivo recomendado por las Guías en pacientes con IC e insuficiencia mitral FUNCIONAL

Directrices	TRC o ICD	Reparación transcatéter o percutánea de borde a borde (MitraClip)	Monitoreo hemodinámico (CardioMems)
ACC/AHA 2013 Directrices sobre insuficiencia cardíaca (las mismas que en 2017)[1.]	Clase I de la COR NDE A (SCD)	Clase IIb de la COR NDE B (transcatéter)	Ninguno
2014 y 2017 Directrices valvulares de ACC/AHA [2]	Clase I de la COR NDE A	Clase IIb de la COR NDE C (de borde a borde)*	Ninguno
SEC 2016 Directrices de la insuficiencia cardíaca [3]	Clase I de la COR NDE A, B	Considerar de borde a borde	Clase IIb Nivel B
SEC 2017 Directrices valvulares [4]	Parte de GDMT si se indica	Clase IIb de la COR NDE C (reparación de borde a borde)	Ninguno

***Recomendado solo para el tratamiento de la IM primaria**

1. Yancy CW et al. 2013 ACCF/AHA Heart Failure Guideline. JACC 62 (16):1495-539. Sin cambios en las actualizaciones 2017
2. Nishimura et al. JACC 2014;63:e57-185; JACC 2017 70:252-289 (sin cambios en las actualizaciones 2017)
3. Ponikowski P et al., 2016 ESC Heart Failure Guidelines. EHJ 37:2129-2200
4. Baumgartner H et al., 2017 ESC/EACTS Valve Guidelines. EHJ 00; 1-53

NNT para evitar 1 muerte por todas las causas*



1. Packer M, Bristow MR, Cohn JN, et al. N Engl J Med 1996;334:1349-1355.
2. The SOLVD Investigators. N Engl J Med 1991;325:293-302.
3. Swedberg K, Komajda M, Bohm M, et al. Lancet 2010;376:1988.
4. Zannad F, McMurray JJV, Krum H, et al. N Engl J Med 2011;364:11-21.
5. McMurray JJV, Packer M, Desai AS, et al. N Engl J Med 2014;371:993-1004.
6. Mack M, et al. TCT 2019

* Datos de diferentes ensayos clínicos
* Beneficios adicionales debido a fármaco de prueba o dispositivo más allá de la terapia de fondo
\# Para la población IT, incluidos los pacientes que pasen al grupo del dispositivo en el grupo de control inicialmente asignado (permitido por protocolo después de 24 meses)

Perfil Clínico de MitraClip?

- Procedimiento:
  - Complejo (pero no tanto, se necesita experiencia y volumen).
  - Seguridad:
    - Mutliples Registros y RCT
  - Eficacia:
    - Sobrevidad / Mortalidad
    - Mejora Calidad de Vida
    - Mejora CF NYHA- Test Caminata 6’
    - Impacto a Largo Plazo
    - Remodelado Ventricular
    - Economia de la Salud

MitraClip en la IM:

Sobrevida

MitraClip en la IM: Sobrevida

- **Estudios Clinicos**
  - EVEREST II RCT
  - EVEREST II HRR
  - REALISM Continued Access Study - Non-HR
  - REALISM Continued Access Study - HR
  - PR PMR
  - Estudio COAPT
  - STS/ACC TVT Registry
  - TRAMI Registry

MitraClip en la IM: Sobrevida EVEREST II RCT

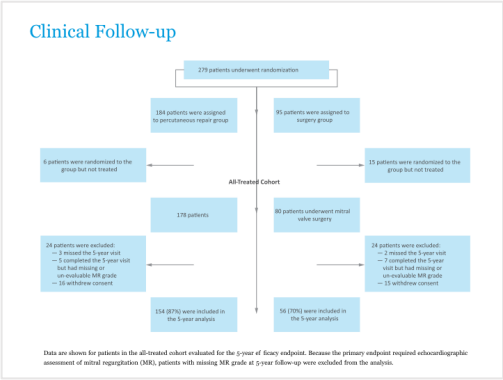
DESCRIPCIÓN GENERAL DEL ESTUDIO

JOURNAL OF THE AMERICAN COLLEGE OF CARDIOLOGY VOL. 66, NO. 25, 2015
© 2015 BY THE AMERICAN COLLEGE OF CARDIOLOGY FOUNDATION ISSN 0735-1097/$36.00
PUBLISHED BY ELSEVIER INC. http://dx.doi.org/10.1016/j.jacc.2015.10.014

Randomized Comparison of Percutaneous Repair and Surgery for Mitral Regurgitation

5-Year Results of EVEREST II

Ted Feldman, MD,* Saibal Kar, MD,† Sammy Elmariah, MD, MPH,‖ Steven C. Smart, MD,* Alfredo Trento, MD,† Robert J. Siegel, MD,† Patricia Apruzzese, MS,† Peter Fail, MD,¶ Michael J. Rinaldi, MD,# Richard W. Smalling, MD, PhD,** James B. Hermiller, MD,†† David Heimansohn, MD,‡‡ William A. Gray, MD,§§ Paul A. Grayburn, MD,‖‖ Michael J. Mack, MD,¶¶ D. Scott Lim, MD,## Goraw Ailawadi, MD,*** Howard C. Herrmann, MD,††† Michael A. Acker, MD,‡‡‡ Frank E. Silvestry, MD,§§§ Elyse Foster, MD,‖‖‖ Andrew Wang, MD,‖‖ Donald D. Glower, MD,¶¶¶ Laura Mauri, MD,### for the EVEREST II Investigators



Clinical Follow-up

279 patients underwent randomization

184 patients were assigned to percutaneous repair group

95 patients were assigned to surgery group

6 patients were randomized to the group but not treated

15 patients were randomized to the group but not treated

All-Treated Cohort

178 patients

80 patients underwent mitral valve surgery

24 patients were excluded:
— 3 missed the 5-year visit
— 5 completed the 5-year visit but had missing or un-evaluable MR grade
— 16 withdrew consent

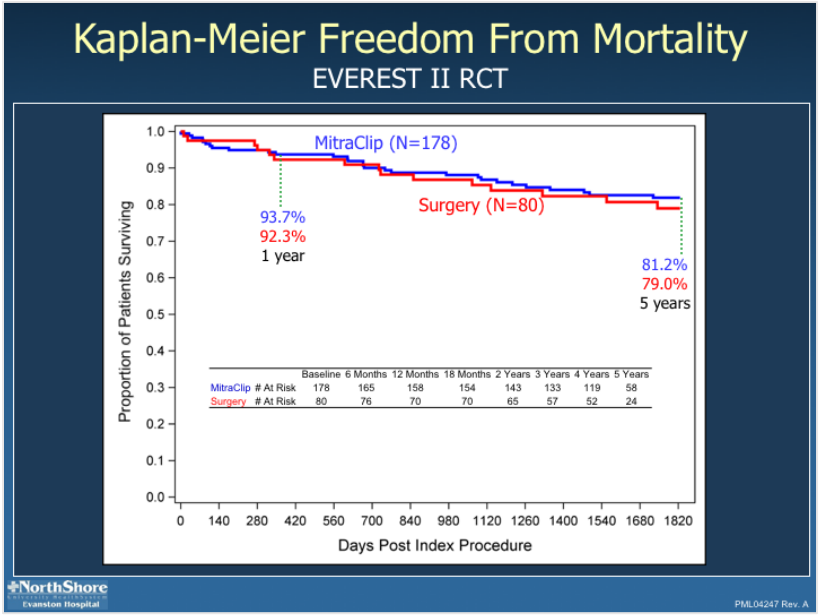
24 patients were excluded:
— 2 missed the 5-year visit
— 7 completed the 5-year visit but had missing or un-evaluable MR grade
— 15 withdrew consent

154 (87%) were included in the 5-year analysis

56 (70%) were included in the 5-year analysis

Data are shown for patients in the all-treated cohort evaluated for the 5-year ef ficacy endpoint. Because the primary endpoint required echocardiographic assessment of mitral regurgitation (MR), patients with missing MR grade at 5-year follow-up were excluded from the analysis.

RESULTADOS CLAVE



- Feldman et al 2015- JACC VOL. 66, NO. 25:2844–54
  Feldman T. Final Results of the EVEREST II Randomized Controlled Trial of Percutaneous and Surgical Reduction of Mitral Regurgitation. Presented at ACC 2014.

MitraClip en la IM: Sobrevida REALISM Non-HR

DESCRIPCIÓN GENERAL DEL ESTUDIO

RESULTADOS CLAVE

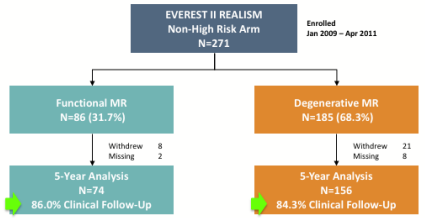
The EVEREST II REALISM Continued Access Non-High Risk Study:
Mid- and Long-Term Follow-up in Surgical Candidates

Ted Feldman MD, Saibal Kar MD, D Scott Lim MD, Richard Smalling MD, Brian Whisenant MD, Chad Rammohan MD, Peter Fail MD, Michael Rinaldi MD, James Hermiller MD, Howard Herrmann MD, Robert Kipperman MD, James Slater MD, Elyse Foster MD, Neil J. Weissman MD, and Donald Glower MD
On behalf of the EVEREST II Investigators

ESC 2017
August 28, 2017

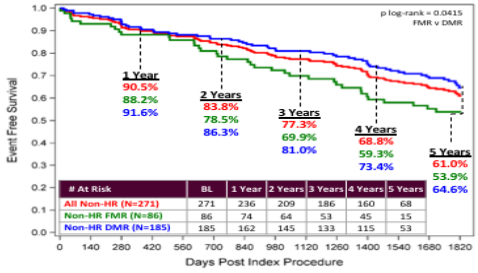
EVEREST II REALISM (NCT01931956) funded by Abbott Vascular. Investigators received research support from Abbott Vascular.

Clinical Follow-Up
EVEREST II REALISM Non-High Risk



ESC CONGRESS BARCELONA 2017 #esccongress www.escardio.org/ESC2017

EVEREST II REALISM Non-High Risk
Kaplan-Meier Estimate of Freedom From All-Cause Mortality
All Non-HR, FMR & DMR Subgroups



ESC CONGRESS BARCELONA 2017 #esccongress www.escardio.org/ESC2017

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FUNDACIÓN FAVALORO HOSPITAL UNIVERSITARIO

MitraClip en la IM: Sobrevida REALISM HR

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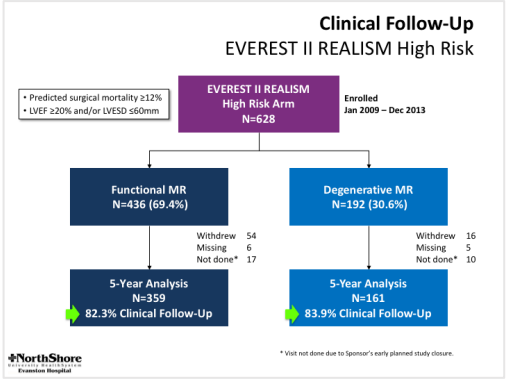

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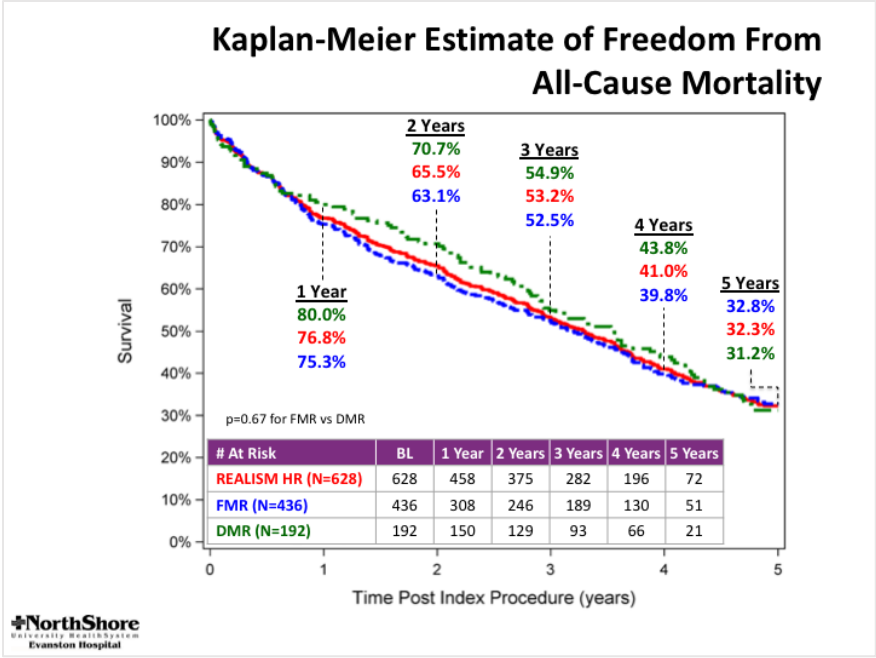

- Feldman T. The EVEREST II REALISM Continued Access Study: Five Year Outcomes in High Surgical Risk Patients. Presented at EuroPCR 2018.

MitraClip en la IM: Sobrevida IM Degenerativa

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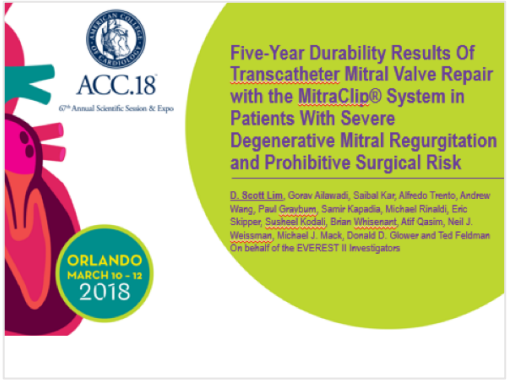

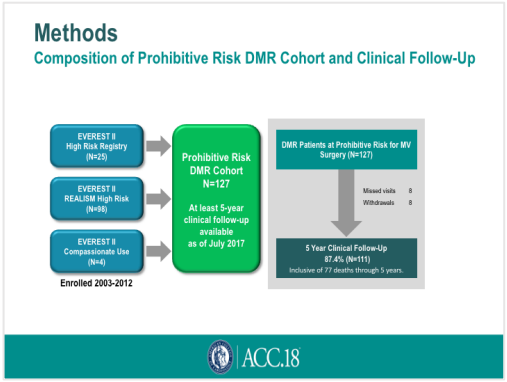

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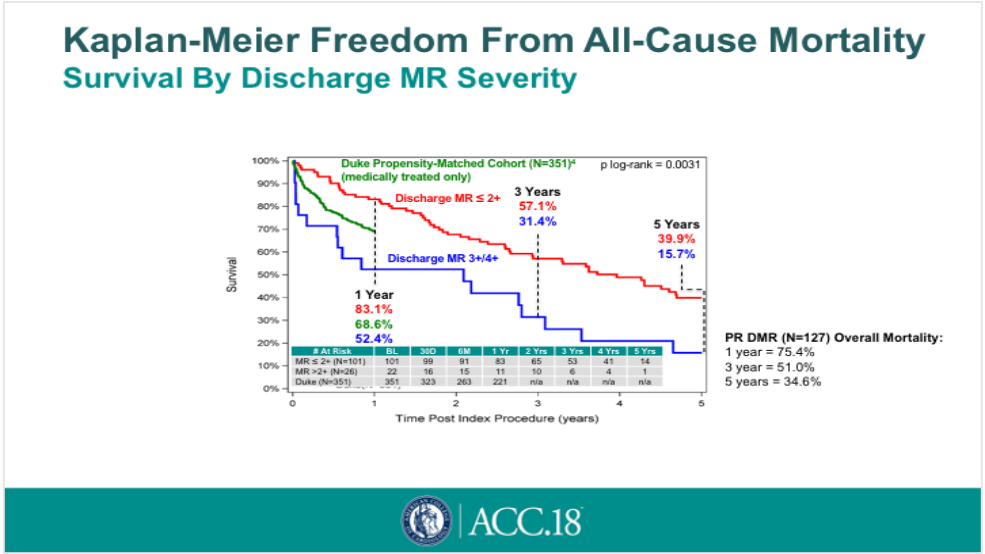

- Lim S, Aliwadi G, Kar S, et al. Five-Year Durability Results of Transcatheter Mitral Valve Repair with the MitraClip® System in Patients With Severe Degenerative Mitral Regurgitation and Prohibitive Surgical Risk. Presented at ACC 2018.

MitraClip en la IM: Sobrevida COAPT Trial

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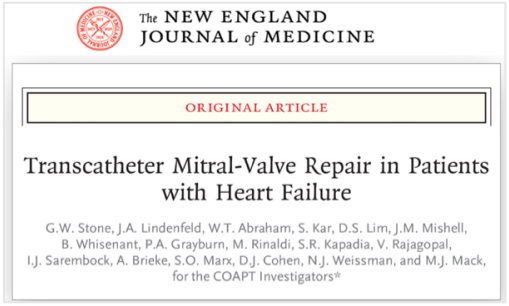

The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

Transcatheter Mitral-Valve Repair in Patients with Heart Failure

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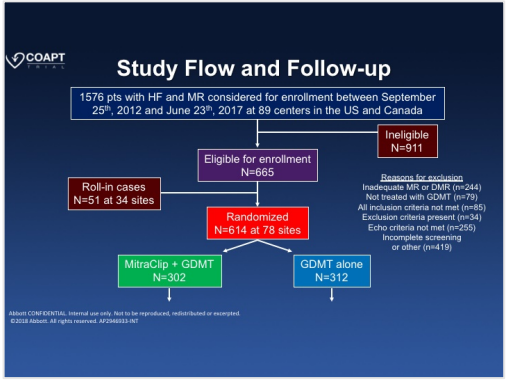

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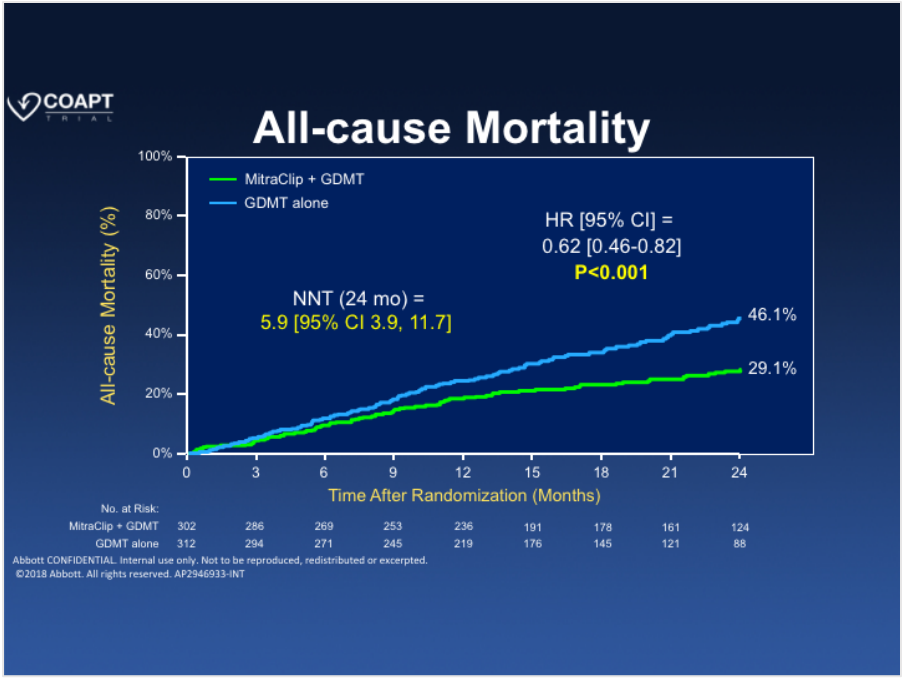

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MitraClip en la IM: Sobrevida TVT Registry

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JOURNAL OF THE AMERICAN COLLEGE OF CARDIOLOGY
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PUBLISHED BY ELSEVIER

VOL. 70, NO. 19, 2017
ISSN 0735-1097/$36.00
https://doi.org/10.1016/j.jacc.2017.09.015

ORIGINAL INVESTIGATIONS

Outcomes With Transcatheter Mitral Valve Repair in the United States

An STS/ACC TVT Registry Report

Paul Sorajja, MD,[a] Sreekanth Vemulapalli, MD,[b] Ted Feldman, MD,[c] Michael Mack, MD,[d] David R. Holmes, Jr, MD,[e] Amanda Stebbins, MS,[b] Saibal Kar, MD,[f] Vinod Thourani, MD,[g] Gorav Ailawadi, MD[h]

Data Analysis

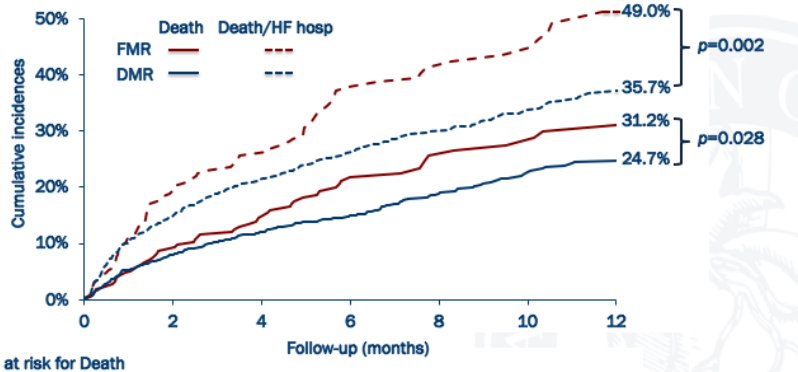
- Patient characteristics, procedural, and in-hospital events sourced from TVT registry (n=2,952)
  - Acute procedural success defined as post-procedural MR ≤2, without surgery or death
- 30-day and 1-year events from linked CMS claims data (n=1,867 or 63%)
  - Examined death, MV surgery, and re-hospitalization for heart failure

STS/ACC TVT Registry

The Society of Thoracic Surgeons | AMERICAN COLLEGE of CARDIOLOGY

RESULTADOS CLAVE

Etiology of MR and Outcome



STS/ACC TVT Registry

The Society of Thoracic Surgeons | AMERICAN COLLEGE of CARDIOLOGY

Sorajja P. et al. Clinical Outcomes at 1-year after Commercial Transcatheter Mitral Valve Repair in the United States: An STS/ACC TVT Registry Report. Presented at ACC 2017
Sorajja P, Vemulapalli S, Feldman T, et al. Outcomes With Transcatheter Mitral Valve Repair in the United States: An STS/ACC TVT Registry Report. *J Am Coll Cardiol*. 2017;70(19):2315-2327.

FUNDACIÓN FAVALORO HOSPITAL UNIVERSITARIO

MitraClip en la IM: Sobrevida TRAMI

DESCRIPCIÓN GENERAL DEL ESTUDIO

Contents lists available at ScienceDirect

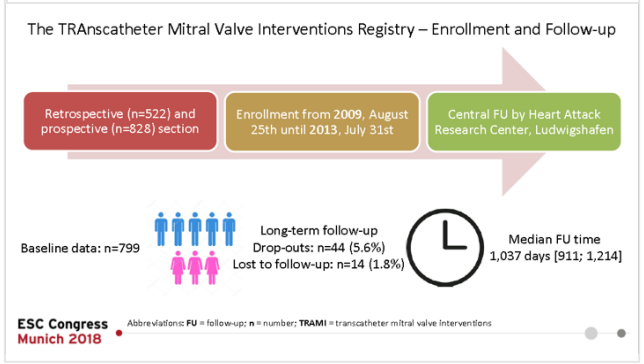
International Journal of Cardiology

journal homepage: www.elsevier.com/locate/ijcard

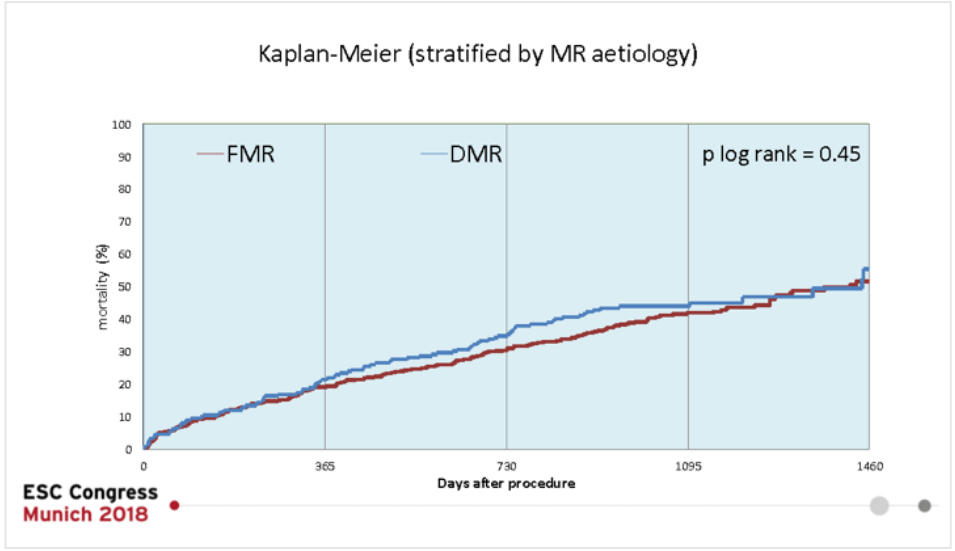
Long-term outcome, survival and predictors of mortality after MitraClip therapy: Results from the German Transcatheter Mitral Valve Interventions (TRAMI) registry☆

Daniel Kalbacher [a], Ulrich Schäfer [a], R. Stephan v. Bardeleben [b], Holger Eggebrecht [c], Horst Sievert [d], Georg Nickenig [e], Christian Butter [f], Andreas E. May [g], Raffi Bekeredjian [h], Taoufik Ouarrak [i], Karl-Heinz Kuck [j], Björn Plicht [k], Ralf Zahn [l], Stephan Baldus [m], Hüseyin Ince [n], Wolfgang Schillinger [o], Peter Boekstegers [p], Jochen Senges [i], Edith Lubos [a,*]

* Universitäres Herzzentrum Hamburg Frankfurt Germany



RESULTADOS CLAVE



Kalbacher D, Schäfer U, V Bardeleben RS, et al. Long-term outcome, survival and predictors of mortality after MitraClip therapy: Results from the German Transcatheter Mitral Valve Interventions (TRAMI) registry. *Int J Cardiol.* 2018; pii: S0167-5273(18)32310-6.
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MitraClip en la IM:

Calidad de Vida

MitraClip en la IM: Mejora Calidad de Vida

- **Estudios Clinicos**
  - EVEREST II RCT
  - EVEREST II HRR
  - REALISM Continued Access Study - Non-HR
  - REALISM Continued Access Study – HR
  - PR PMR
  - Estudio COAPT
  - Estudio MITRA-FR
  - TRAMI Registry

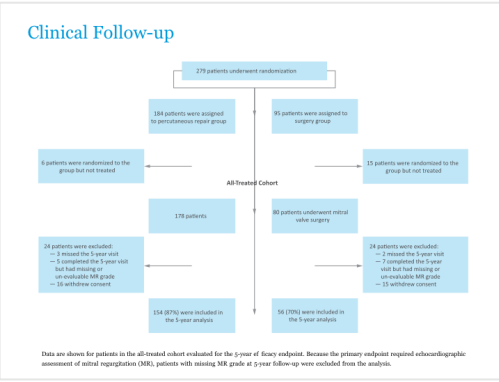
MitraClip en la IM: Mejora Calidad de Vida EVEREST II RCT

DESCRIPCIÓN GENERAL DEL ESTUDIO

Randomized Comparison of Percutaneous Repair and Surgery for Mitral Regurgitation

5-Year Results of EVEREST II

Ted Feldman, MD,* Saibal Kar, MD,† Sammy Elmariah, MD, MPH,‡§ Steven C. Smart, MD,* Alfredo Trento, MD,‖ Robert J. Siegel, MD,† Patricia Apruzzese, MS,‖ Peter Fail, MD,¶ Michael J. Rinaldi, MD,# Richard W. Smalling, MD, PsD,** James B. Hermiller, MD,†† David Heimansohn, MD,‡‡ William A. Gray, MD,§§ Paul A. Grayburn, MD,‖‖ Michael J. Mack, MD,¶¶ D. Scott Lim, MD,## Gorav Ailawadi, MD,*** Howard C. Herrmann, MD,††† Michael A. Acker, MD,‡‡‡ Frank E. Silvestry, MD,§§§ Elyse Foster, MD,‖‖‖ Andrew Wang, MD,¶¶¶ Donald D. Glower, MD,### Laura Mauri, MD,#### for the EVEREST II Investigators



Data are shown for patients in the all-treated cohort evaluated for the 5-year ef ficacy endpoint. Because the primary endpoint required echocardiographic assessment of mitral regurgitation (MR), patients with missing MR grade at 5-year follow-up were excluded from the analysis.

RESULTADOS CLAVE

EVEREST II
Improvement in Quality of Life (SF-36)

- At 12 months, there were statistically significant improvements in the QoL measured by the SF-36; with a 4.4 increase in the physical component ($p<0.001$) and 5.7 increase in the mental component ($p<0.0001$).

PERCUTANEOUS REPAIR (N=184)	Number of Patients	Value	P Value for Comparison between Baseline and 12 Mo
Change from baseline in quality-of-life score†			
30 days			
Physical component summary	147	3.1±9.4	<0.001
Mental component summary	148	4.4±11.3	<0.001
12 months			
Physical component summary	132	4.4±9.8	<0.001
Mental component summary	133	5.7±9.9	<0.001

- Feldman T. Final Results of the EVEREST II Randomized Controlled Trial of Percutaneous and Surgical Reduction of Mitral Regurgitation. Presented at ACC 2014.
- Feldman T, Foster E, Glower DD, et al. Percutaneous repair or surgery for mitral regurgitation. *N Engl J Med.* 2011;364(15):1395-1406.

MitraClip en la IM: Mejora Calidad de Vida EVEREST II HRR

DESCRIPCIÓN GENERAL DEL ESTUDIO

Valvular heart disease

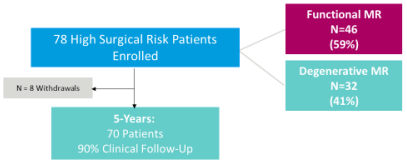
ORIGINAL RESEARCH ARTICLE

Five-year outcomes of transcatheter reduction of significant mitral regurgitation in high-surgical-risk patients

Saibal Kar,[1,2] Ted Feldman,[3] Atif Qasim,[4] Alfredo Trento,[1] Samir Kapadia,[5] Wesley Pedersen,[6] D Scott Lim,[7] Robert Kipperman,[8] Richard W Smalling,[9] Tanvir Bajwa,[10] Howard C Hermann,[11] James B Hermiller,[12] John M Lasala,[13] Mark Reisman,[14] Donald Glower,[15] Laura Mauri,[16] Patrick Whitlow,[5] on behalf of the EVEREST II Investigators

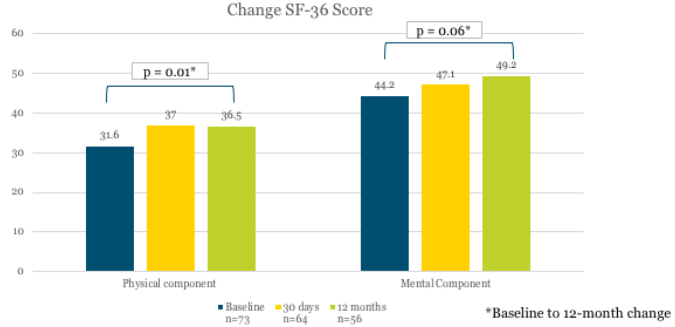
EVEREST II HRR
Study Design and Clinical Follow-up

- Symptomatic patients with significant MR (≥3+)
- Surgical risk based on a STS calculated risk score ≥12% or a surgeon estimated risk score ≥12% based on prespecified criteria
- Left ventricular function: EF>20%; LVESD<60mm
- Mitral valve anatomy suitable for the MitraClip® Device



RESULTADOS CLAVE

EVEREST II HRR
Quality of Life (SF-36)



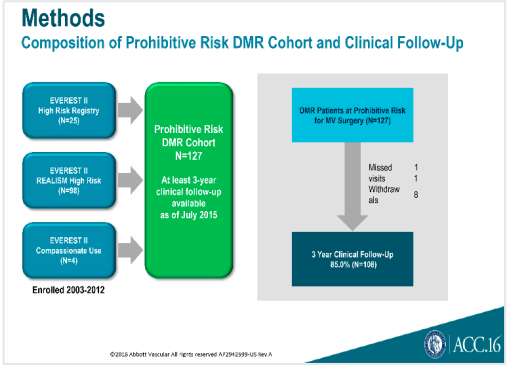
Clinical Results at Baseline and Follow-up

Clinical Parameter	Baseline (n = 78)	30 days (n = 72)	6 Months (n = 63)	12 Months (n = 56)	Baseline to 12-Month Change* p Value
MR grade ≤2+†	1.3 (1/78)	72.9 (51/70)	73.3 (44/60)	77.8 (42/54)	<0.0001
NYHA functional class I/II‡	10.2 (8/78)	73.2 (52/71)	80.3 (49/61)	74.1 (40/54)	<0.0001
NYHA functional class III/IV‡	89.8 (70/78)	26.8 (19/71)	19.7 (12/61)	25.9 (14/54)	<0.0001
Quality of life, SF-36 score					
Physical component, n = 47	31.6 ± 9.1 (73/78)	37.0 ± 9.7 (64)	N/A	36.5 ± 10.6 (51)	0.01
Mental component, n = 47	44.2 ± 12.6 (73/78)	47.1 ± 12.4 (64)	N/A	49.2 ± 12.0 (51)	0.06

- Kar S, Feldman T, Qasim A, et al Five-year outcomes of transcatheter reduction of significant mitral regurgitation in high-surgical-risk patients Heart Published Online First: 04 August 2018. doi: 10.1136/heartjnl-2017-312605
- Kar S, Whitlow P, Pedersen W, et al. Effectiveness Of Transcatheter Reduction Of Significant Mitral Regurgitation In High Surgical Risk Patients With Mitraclip: Final 5 Year Results Of The EVEREST II High Risk Registry. Journal of the American College of Cardiology Apr 2014, 63 (12 Supplement) A1683; DOI: 10.1016/S0735-1097(14)61686-7. Presented at ACC 2014 - Presentation Number 2901-04.

MitraClip en la IM: Mejora Calidad de Vida PR IM Degenerativa

DESCRIPCIÓN GENERAL DEL ESTUDIO



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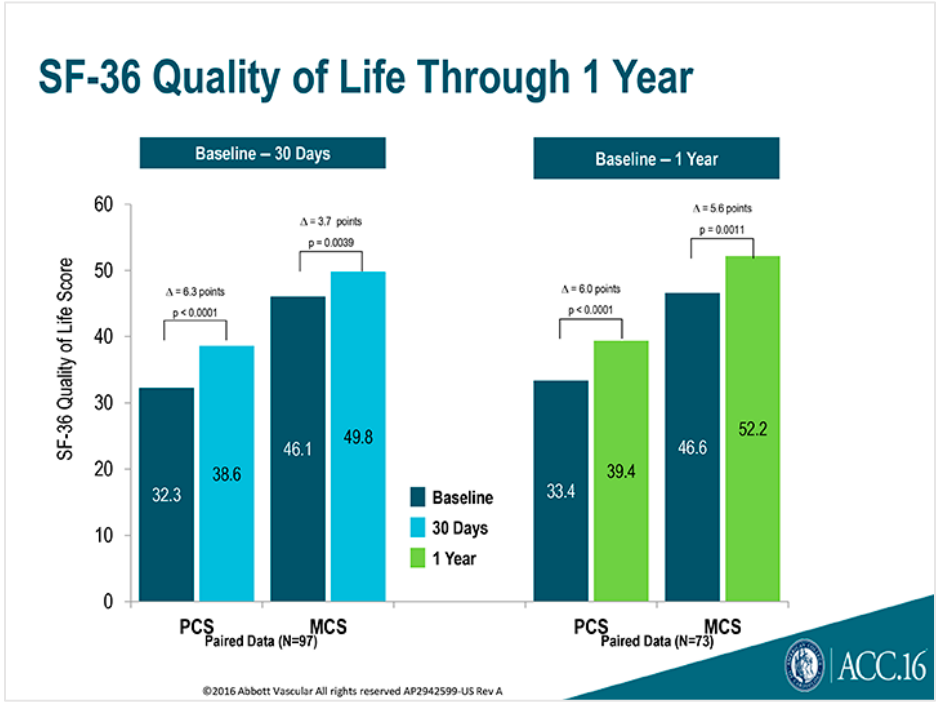

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MitraClip en la IM: Mejora Calidad de Vida COAPT

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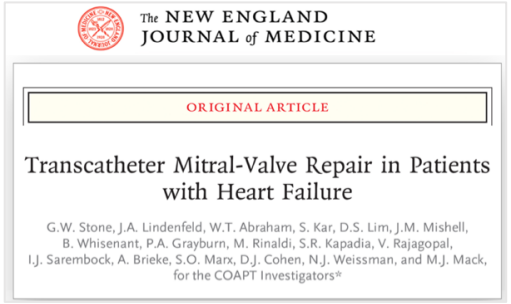

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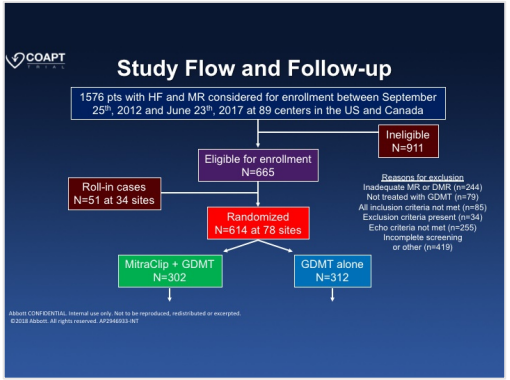

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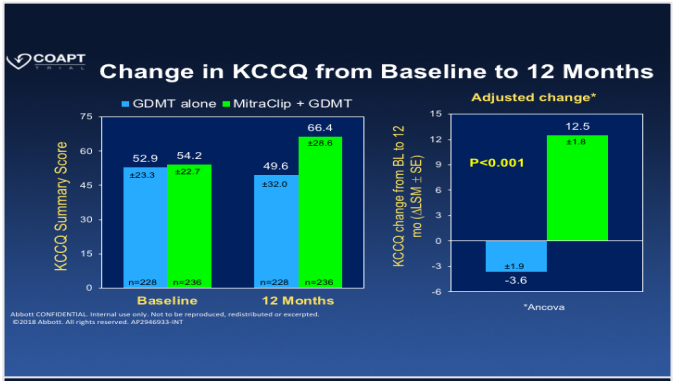

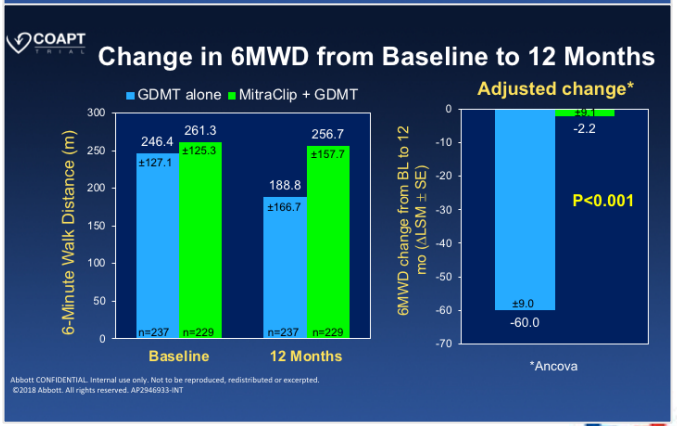

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MitraClip en la IM:

Mejora la CF y el Test de Caminata a 6’

MitraClip en la IM: CF NYHA Caminata 6’

- **Estudios**
  - EVEREST II RCT
  - EVEREST II HRR
  - REALISM Continued Access Study - Non-HR
  - REALISM Continued Access Study - HR
  - PR PMR
  - Estudio COAPT
  - MITRA FR
  - TRAMI Registry

MitraClip en la IM: CF NYHA Caminata 6’ EVEREST II RCT

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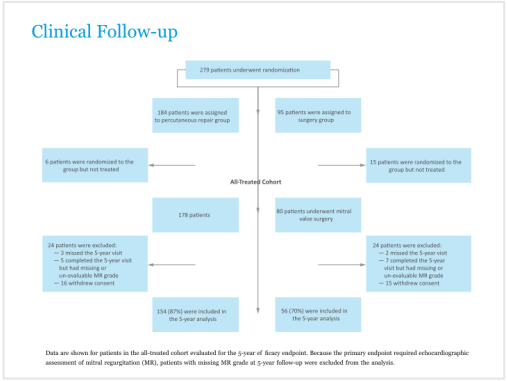

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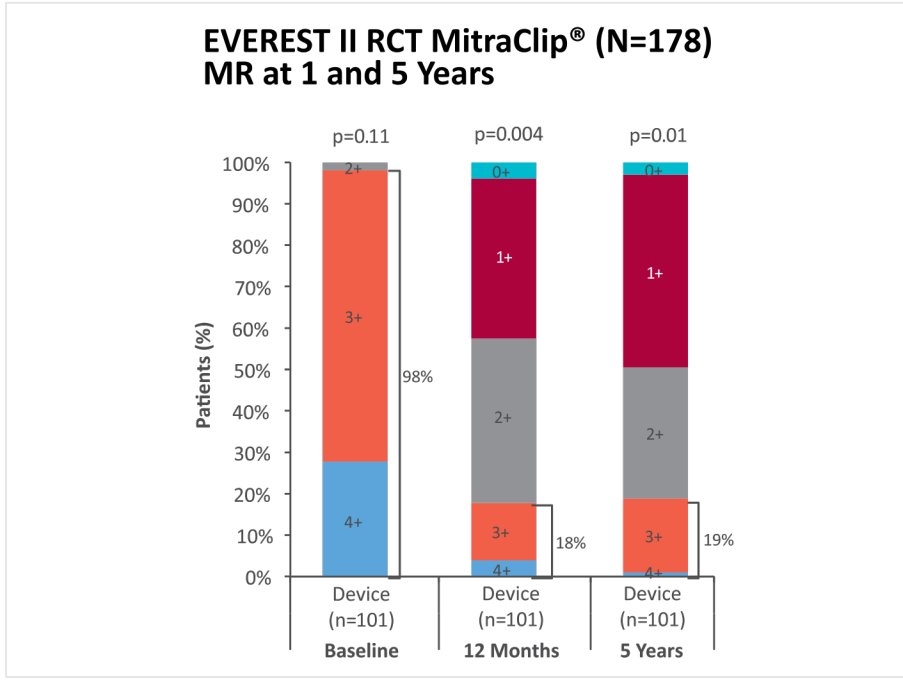

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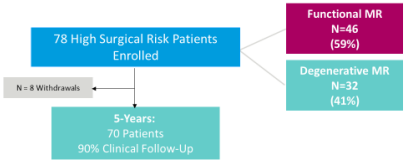

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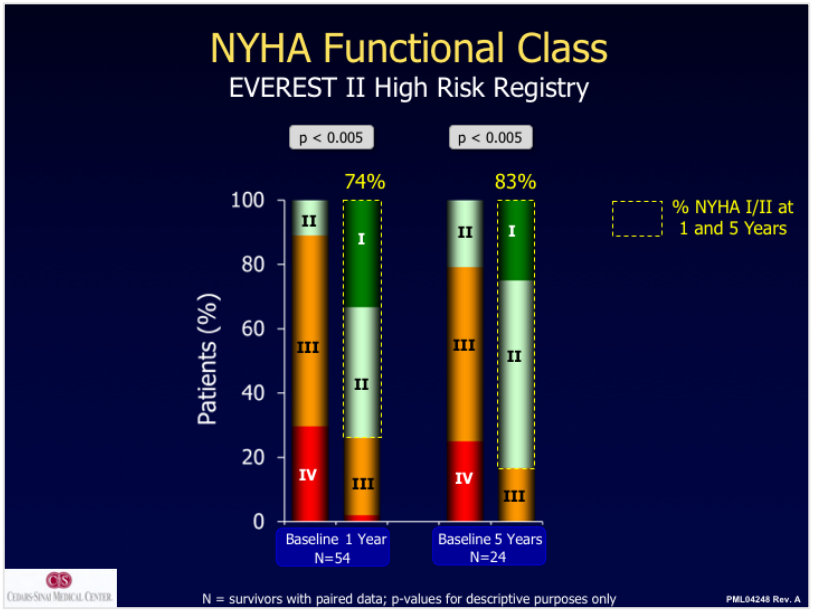

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- Kar S, Whitlow P, Pedersen W, et al. Effectiveness Of Transcatheter Reduction Of Significant Mitral Regurgitation In High Surgical Risk Patients With Mitraclip: Final 5 Year Results Of The EVEREST II High Risk Registry. Journal of the American College of Cardiology Apr 2014, 63 (12 Supplement) A1683; DOI: 10.1016/S0735-1097(14)61686-7. Presented at ACC 2014 - Presentation Number 2901-04.

MitraClip en la IM: CF NYHA Caminata 6’ REALISM Non-HR

DESCRIPCIÓN GENERAL DEL ESTUDIO

The EVEREST II REALISM Continued Access Non-High Risk Study:
Mid- and Long-Term Follow-up in Surgical Candidates

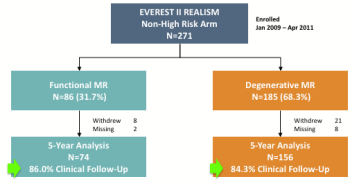
Ted Feldman MD, Saibal Kar MD, D Scott Lim MD, Richard Smalling MD, Brian Whisenant MD, Chad Rammohan MD, Peter Fail MD, Michael Rinaldi MD, James Hermiller MD, Howard Herrmann MD, Robert Kipperman MD, James Slater MD, Elyse Foster MD, Neil J. Weissman MD, and Donald Glower MD
On behalf of the EVEREST II Investigators

ESC 2017
August 28, 2017

EVEREST II REALISM (NCT01931956) funded by Abbott Vascular. Investigators received research support from Abbott Vascular.

ESC CONGRESS BARCELONA 2017 #esccongress www.escardio.org/ESC2017

Clinical Follow-Up
EVEREST II REALISM Non-High Risk



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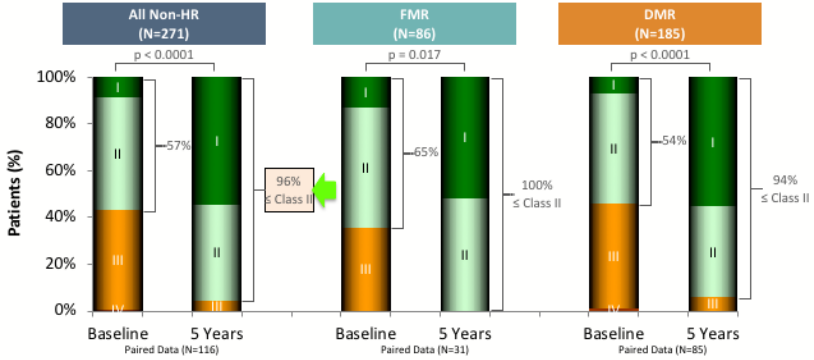
RESULTADOS CLAVE

REALISM NHRR 5-year (N=271)
NYHA Functional Class
Paired Analysis Baseline – 5 Years



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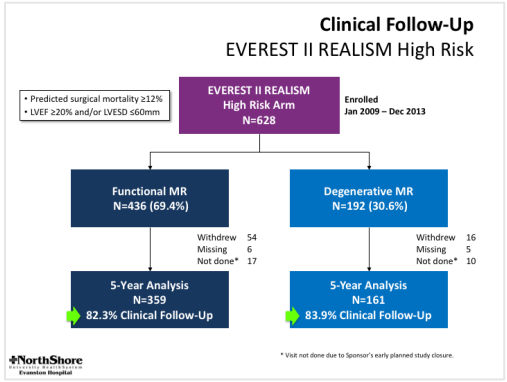
- Feldman T. The EVEREST II REALISM Continued Access Non-High Risk Study: Mid- and Long-Term Follow-up in Surgical Candidates. Presented at ESC 2017.

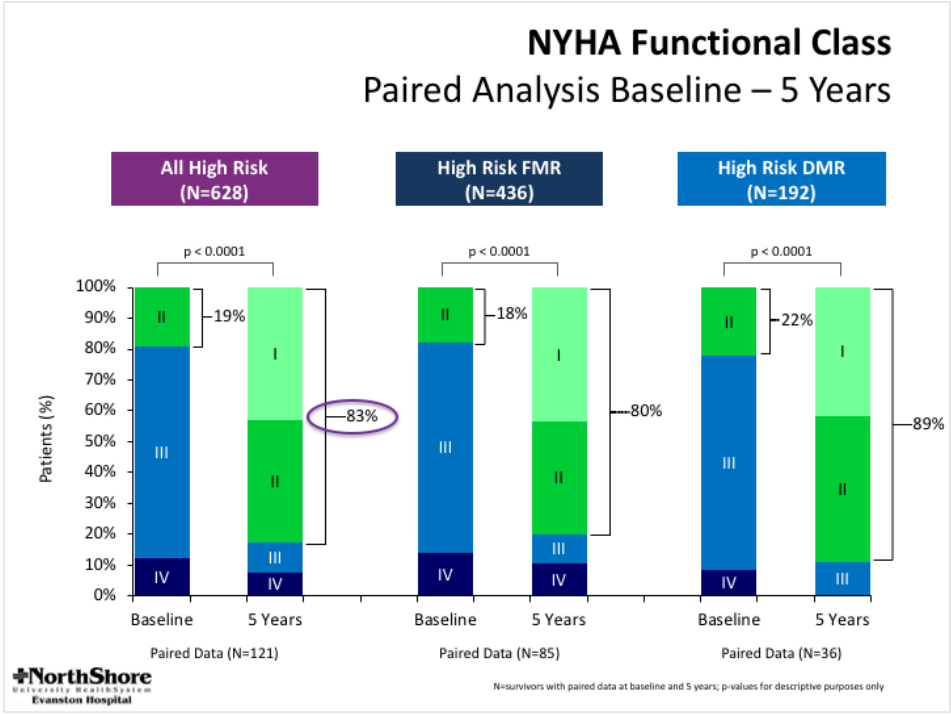
FUNDACIÓN FAVALORO HOSPITAL UNIVERSITARIO

MitraClip en la IM: CF NYHA Caminata 6’ REALISM HR

DESCRIPCIÓN GENERAL DEL ESTUDIO



RESULTADOS CLAVE

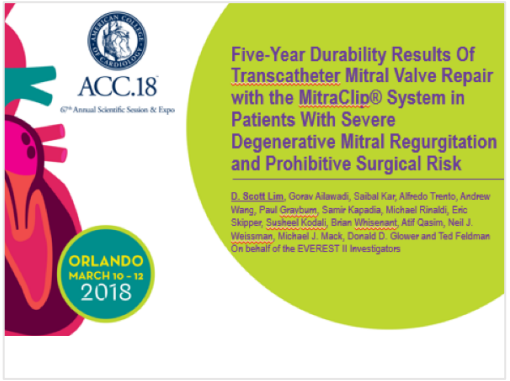


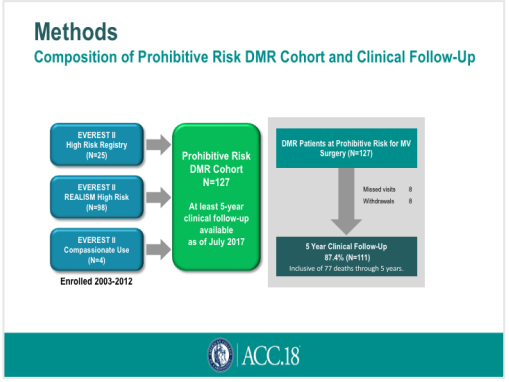
- Feldman T. The EVEREST II REALISM Continued Access Study: Five Year Outcomes in High Surgical Risk Patients. Presented at EuroPCR 2018.

FUNDACIÓN FAVALORO HOSPITAL UNIVERSITARIO

MitraClip en la IM: CF NYHA Caminata 6’ PR IM Degenerativa

DESCRIPCIÓN GENERAL DEL ESTUDIO





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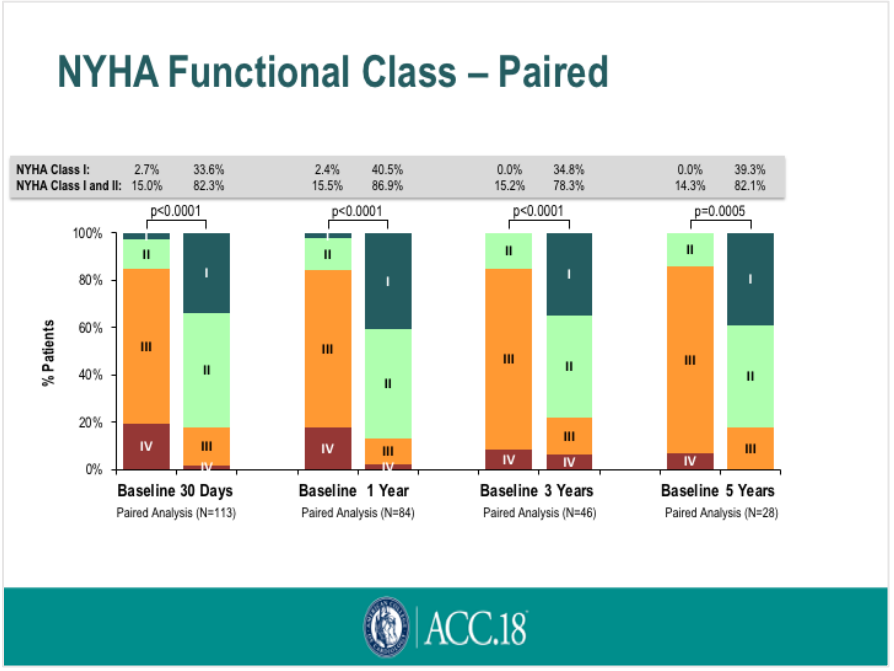
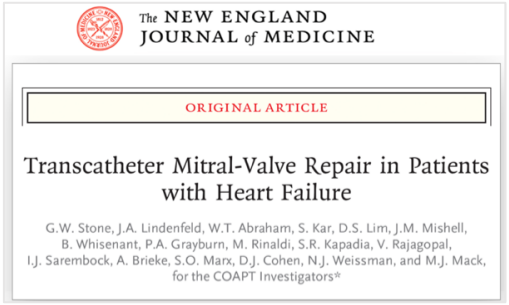


- Lim S, Aliwadi G, Kar S, et al. Five-Year Durability Results of Transcatheter Mitral Valve Repair with the MitraClip® System in Patients With Severe Degenerative Mitral Regurgitation and Prohibitive Surgical Risk. Presented at ACC 2018.

MitraClip en la IM: CF NYHA Caminata 6' COAPT

DESCRIPCIÓN GENERAL DEL ESTUDIO

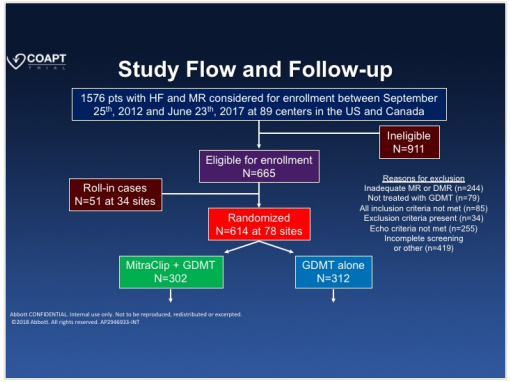


The NEW ENGLAND JOURNAL of MEDICINE

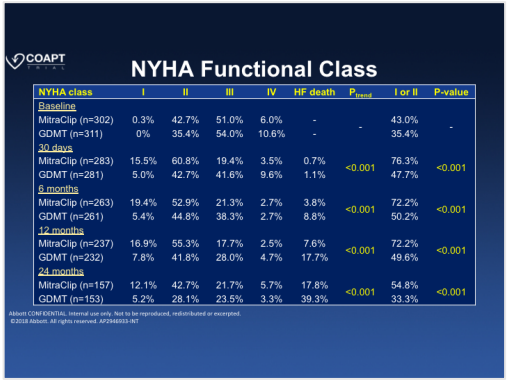
ORIGINAL ARTICLE

Transcatheter Mitral-Valve Repair in Patients with Heart Failure

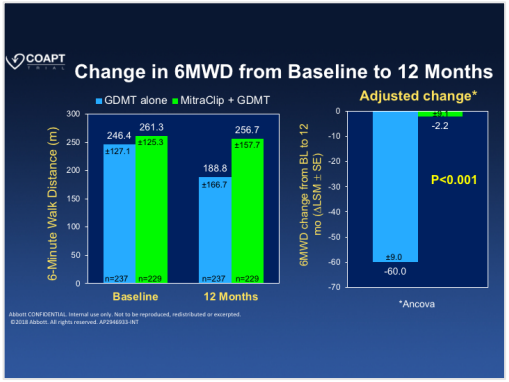
G.W. Stone, J.A. Lindenfeld, W.T. Abraham, S. Kar, D.S. Lim, J.M. Mishell, B. Whisenant, P.A. Grayburn, M. Rinaldi, S.R. Kapadia, V. Rajagopal, I.J. Saremberk, A. Brieke, S.O. Marx, D.J. Cohen, N.J. Weissman, and M.J. Mack, for the COAPT Investigators*



RESULTADOS CLAVE



NYHA class	I	II	III	IV	HF death	P_{trend}	I or II	P-value
Baseline								
MitraClip (n=302)	0.3%	42.7%	51.0%	6.0%	-		43.0%	
GDMT (n=311)	0%	35.4%	54.0%	10.6%	-	-	35.4%	-
30 days								
MitraClip (n=283)	15.5%	60.8%	19.4%	3.5%	0.7%		76.3%	
GDMT (n=281)	5.0%	42.7%	41.6%	9.6%	1.1%	<0.001	47.7%	<0.001
6 months								
MitraClip (n=263)	19.4%	52.9%	21.3%	2.7%	3.8%		72.2%	
GDMT (n=261)	5.4%	44.8%	38.3%	2.7%	8.8%	<0.001	50.2%	<0.001
12 months								
MitraClip (n=237)	16.9%	55.3%	17.7%	2.5%	7.6%		72.2%	
GDMT (n=232)	7.8%	41.8%	28.0%	4.7%	17.7%	<0.001	49.6%	<0.001
24 months								
MitraClip (n=157)	12.1%	42.7%	21.7%	5.7%	17.8%		54.8%	
GDMT (n=153)	5.2%	28.1%	23.5%	3.3%	39.3%	<0.001	33.3%	<0.001



- Stone GW et al NEJM 2018 (DOI: 10.1056/NEJMoa1806640).
  Stone G. COAPT: A Randomized Trial of Transcatheter Mitral Valve Leaflet Approximation in Patients with Heart Failure and Secondary Mitral Regurgitation. Presented at TCT 2018.

MitraClip en la IM: CF NYHA Caminata 6’ Mitra-FR

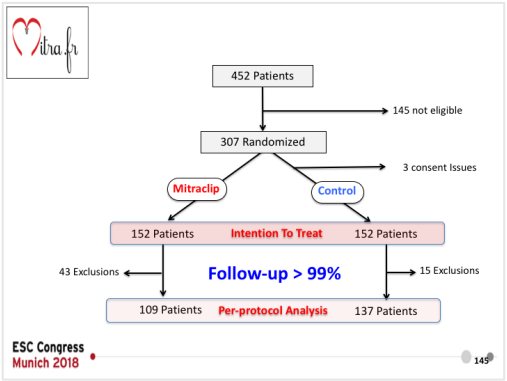
DESCRIPCIÓN GENERAL DEL ESTUDIO

The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

Percutaneous Repair or Medical Treatment for Secondary Mitral Regurgitation

J.-F. Obadia, D. Messika-Zeitoun, G. Leurent, B. Iung, G. Bonnet, N. Piriou, T. Lefèvre, C. Piot, F. Rouleau, D. Carrié, M. Nejjari, P. Ohlmann, F. Leclercq, C. Saint Etienne, E. Teiger, L. Leroux, N. Karam, N. Michel, M. Gilard, E. Donal, J.-N. Trochu, B. Cormier, X. Armoiry, F. Boutitie, D. Maucort-Boulch, C. Barnel, G. Samson, P. Guerin, A. Vahanian, and N. Mewton, for the MITRA-FR Investigators*

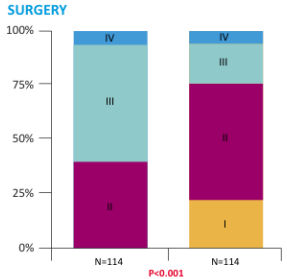


RESULTADOS CLAVE

MITRA-FR

PRESPECIFIED SECONDARY ENDPOINTS

NYHA evolution (paired data)



Secondary Echocardiographic End Points at 12 months

	Percutaneous Repair Group (n=152)		
Change from baseline in echocardiographic measures	N	Value	P value between Baseline and 12 Mo
Effective regurgitant orifice area - mm²	60	-15 [-23.5 ; -8]	<0.0001
End-systolic diameter - mm	89	2 [-2 ; 7]	0.002
Ejection fraction - %	86	-3 [-8 ; 4]	0.14
Pulmonary artery systolic pressure - mmHg	64	-6.5 [-18 ; 4.5]	0.001
6-minute walk variation - m	73	25 [-40 ; 71]	0.08

- Obadia J. et al. NEJM 2018 DOI: 10.1056/NEJMoa1805374
  Obadia J. Percutaneous Repair with the MitraClip device for Severe Secondary Mitral Regurgitation. Presented at ESC 2018.

MitraClip en la IM: CF NYHA Caminata 6’ TRAMI

DESCRIPCIÓN GENERAL DEL ESTUDIO

Contents lists available at ScienceDirect

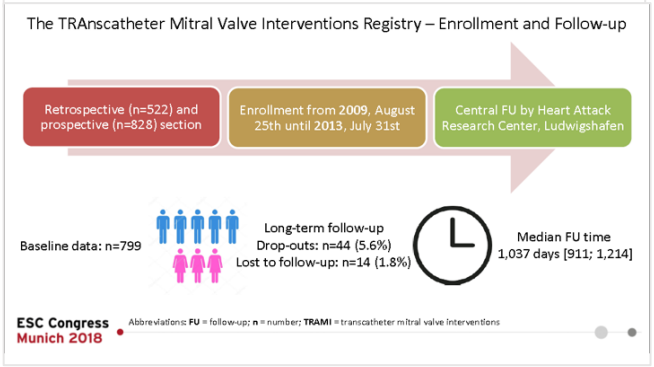
International Journal of Cardiology

journal homepage: www.elsevier.com/locate/ijcard

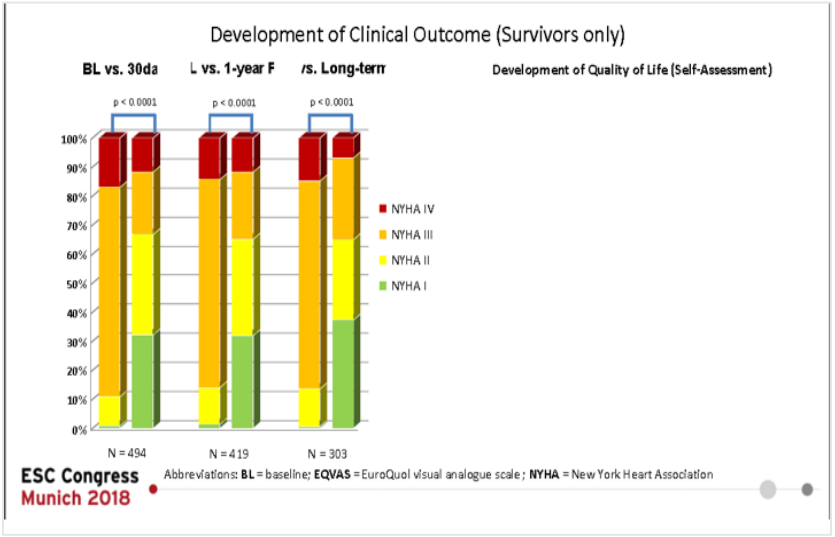
Long-term outcome, survival and predictors of mortality after MitraClip therapy: Results from the German Transcatheter Mitral Valve Interventions (TRAMI) registry☆

Daniel Kalbacher [a], Ulrich Schäfer [a], R. Stephan v. Bardeleben [b], Holger Eggebrecht [c], Horst Sievert [d], Georg Nickenig [e], Christian Butter [f], Andreas E. May [g], Raffi Bekeredjian [h], Taoufik Ouarrak [i], Karl-Heinz Kuck [j], Björn Plicht [k], Ralf Zahn [l], Stephan Baldus [m], Hüseyin Ince [n], Wolfgang Schillinger [o], Peter Boekstegers [p], Jochen Senges [i], Edith Lubos [a,*]

* Universitäres Herzzentrum Hamburg Frauenhaf, Germany



RESULTADOS CLAVE



- Kalbacher D, Schäfer U, V Bardeleben RS, et al. Long-term outcome, survival and predictors of mortality after MitraClip therapy: Results from the German Transcatheter Mitral Valve Interventions (TRAMI) registry. *Int J Cardiol.* 2018; pii: S0167-5273(18)32310-6.
- Kalbacher D, Schäfer U, Bardeleben S, et al. Long-term follow-up in the German TRAnscatheter Mitral Valve Interventions (TRAMI) registry: survival and predictors of mortality. Presented at ESC 2018.

MitraClip en la IM:

Tasa de Reintervenciones

Tasa de Reintervención

- **Estudios**
  - EVEREST II RCT
  - EVEREST II HRR
  - REALISM Continued Access Study - Non-HR
  - REALISM Continued Access Study - HR
  - PR PMR
  - Estudio COAPT
  - STS/ACC TVT Registry
  - TRAMI Registry

MitraClip en la IM: Tasa de Reintervenciones EVEREST II RCT

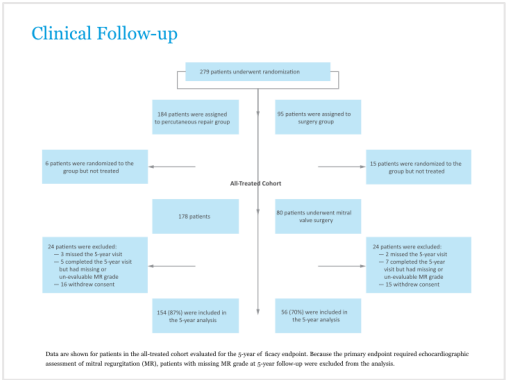
DESCRIPCIÓN GENERAL DEL ESTUDIO

JOURNAL OF THE AMERICAN COLLEGE OF CARDIOLOGY VOL. 66, NO. 25, 2015
© 2015 BY THE AMERICAN COLLEGE OF CARDIOLOGY FOUNDATION ISSN 0735-1097/$36.00
PUBLISHED BY ELSEVIER INC. http://dx.doi.org/10.1016/j.jacc.2015.10.014

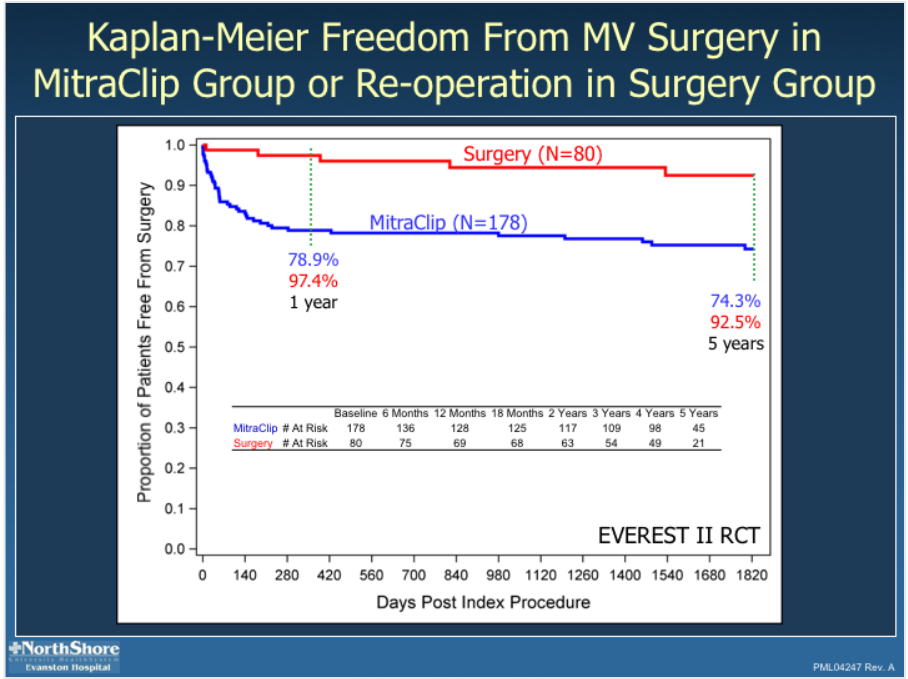
Randomized Comparison of Percutaneous Repair and Surgery for Mitral Regurgitation

5-Year Results of EVEREST II

Ted Feldman, MD,* Saibal Kar, MD,† Sammy Elmariah, MD, MPH,‡§ Steven C. Smart, MD,* Alfredo Trento, MD,‖ Robert J. Siegel, MD,† Patricia Apruzzese, MS,§ Peter Fail, MD,¶ Michael J. Rinaldi, MD,# Richard W. Smalling, MD, PsD,** James B. Hermiller, MD,†† David Heimansohn, MD,‡‡ William A. Gray, MD,§§ Paul A. Grayburn, MD,‖‖ Michael J. Mack, MD,¶¶ D. Scott Lim, MD,## Gorav Ailawadi, MD,*** Howard C. Herrmann, MD,††† Michael A. Acker, MD,‡‡‡ Frank E. Silvestry, MD,††† Elyse Foster, MD,§§§ Andrew Wang, MD,‖‖‖ Donald D. Glower, MD,¶¶¶ Laura Mauri, MD,### for the EVEREST II Investigators



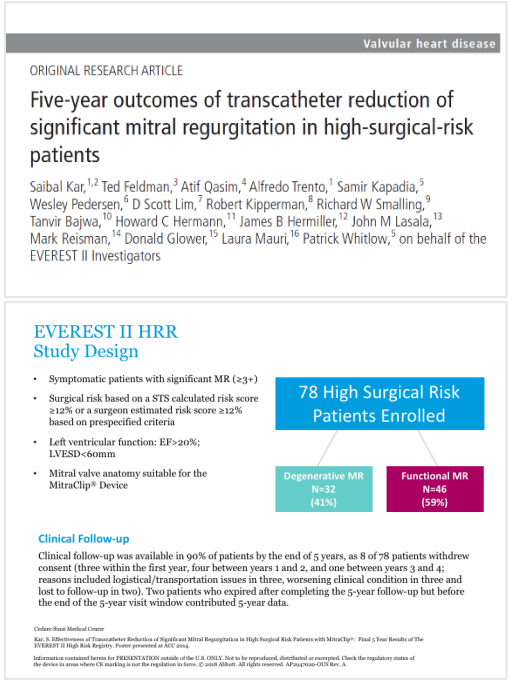
RESULTADOS CLAVE



- Feldman et al. 2015 JACC VOL.66, NO.25:2844–54
  Feldman T. Final Results of the EVEREST II Randomized Controlled Trial of Percutaneous and Surgical Reduction of Mitral Regurgitation. Presented at ACC 2014.

MitraClip en la IM: Tasa de Reintervenciones EVEREST II HRR

DESCRIPCIÓN GENERAL DEL ESTUDIO | **RESULTADOS CLAVE**



Valvular heart disease

ORIGINAL RESEARCH ARTICLE

Five-year outcomes of transcatheter reduction of significant mitral regurgitation in high-surgical-risk patients

Saibal Kar,[1,2] Ted Feldman,[3] Atif Qasim,[4] Alfredo Trento,[1] Samir Kapadia,[5] Wesley Pedersen,[6] D Scott Lim,[7] Robert Kipperman,[8] Richard W Smalling,[9] Tanvir Bajwa,[10] Howard C Hermann,[11] James B Hermiller,[12] John M Lasala,[13] Mark Reisman,[14] Donald Glower,[15] Laura Mauri,[16] Patrick Whitlow,[5] on behalf of the EVEREST II Investigators

EVEREST II HRR
Study Design

- Symptomatic patients with significant MR (≥3+)
- Surgical risk based on a STS calculated risk score ≥12% or a surgeon estimated risk score ≥12% based on prespecified criteria
- Left ventricular function: EF>20%; LVESD<60mm
- Mitral valve anatomy suitable for the MitraClip® Device

78 High Surgical Risk Patients Enrolled

Degenerative MR N=32 (41%)

Functional MR N=46 (59%)

Clinical Follow-up

Clinical follow-up was available in 90% of patients by the end of 5 years, as 8 of 78 patients withdrew consent (three within the first year, four between years 1 and 2, and one between years 3 and 4; reasons included logistical/transportation issues in three, worsening clinical condition in three and lost to follow-up in two). Two patients who expired after completing the 5-year follow-up but before the end of the 5-year visit window contributed 5-year data.

Cedars-Sinai Medical Center

Kar, S. Effectiveness of Transcatheter Reduction of Significant Mitral Regurgitation in High Surgical Risk Patients with MitraClip®: Final 5 Year Results of The EVEREST II High Risk Registry. Poster presented at ACC 2014.

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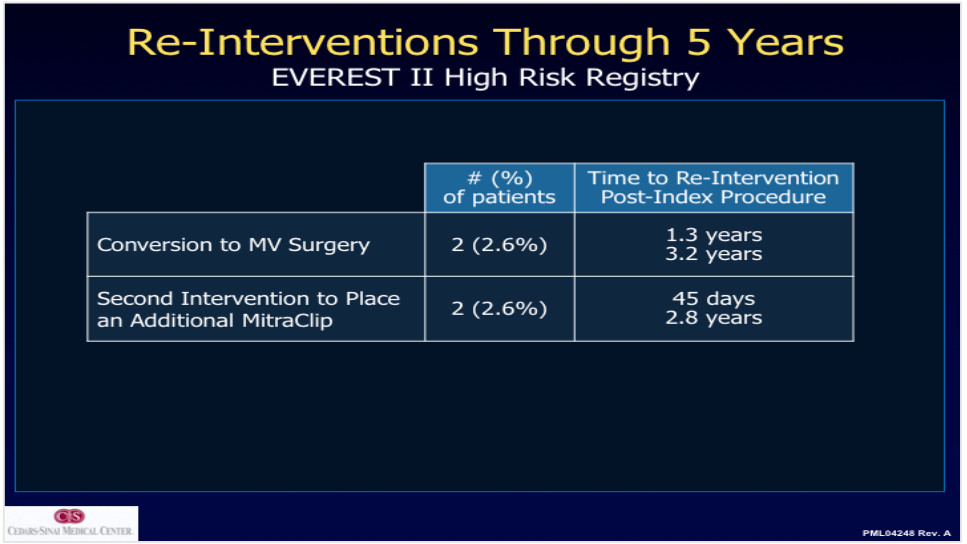

- Kar S, Feldman T, Qasim A, et al Five-year outcomes of transcatheter reduction of significant mitral regurgitation in high-surgical-risk patients Heart Published Online First: 04 August 2018. doi: 10.1136/heartjnl-2017-312605
  Kar S. Effectiveness of Transcatheter Reduction of Significant Mitral Regurgitation in High Surgical Risk Patients with MitraClip®: Final 5 Year Results of The EVEREST II High Risk Registry. Presented at ACC 2014.

MitraClip en la IM: Tasa de Reintervenciones REALISM Non-HR

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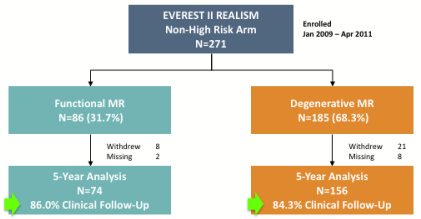
The EVEREST II REALISM Continued Access Non-High Risk Study:
Mid- and Long-Term Follow-up in Surgical Candidates

Ted Feldman MD, Saibal Kar MD, D Scott Lim MD, Richard Smalling MD, Brian Whisenant MD, Chad Rammohan MD, Peter Fail MD, Michael Rinaldi MD, James Hermiller MD, Howard Herrmann MD, Robert Kipperman MD, James Slater MD, Elyse Foster MD, Neil J. Weissman MD, and Donald Glower MD
On behalf of the EVEREST II Investigators

ESC 2017
August 28, 2017

Clinical Follow-Up
EVEREST II REALISM Non-High Risk



RESULTADOS CLAVE

EVEREST II REALISM Non-High Risk
Re-Interventions Through 5 Years

Re-Intervention	EVEREST II REALISM Non-High Risk		
	All Non-High Risk (N=271)	Functional MR (N=86)	Degenerative MR (N=185)
Mitral Valve Surgery Post-Index Procedure	**39 (14.4%)**	**11 (12.8%)**	**28 (15.1%)**
Within 1 Year	28 (10.3%)	9 (10.5%)	19 (10.3%)
Between 1 Year and 5 Years	11 (4.1%)	2 (2.3%)	9 (4.9%)
Second Intervention to Implant an Additional MitraClip Device	**11 (4.1%)**	**3 (3.5%)**	**8 (4.3%)**
Within 1 Year	5 (1.9%)	1 (1.2%)	4 (2.2%)
Between 1 Year and 5 Years	6 (2.2%)	2 (2.3%)	4 (2.2%)

- Feldman T. The EVEREST II REALISM Continued Access Non-High Risk Study: Mid- and Long-Term Follow-up in Surgical Candidates. Presented at ESC 2017.

MitraClip en la IM: Tasa de Reintervenciones REALISM HR

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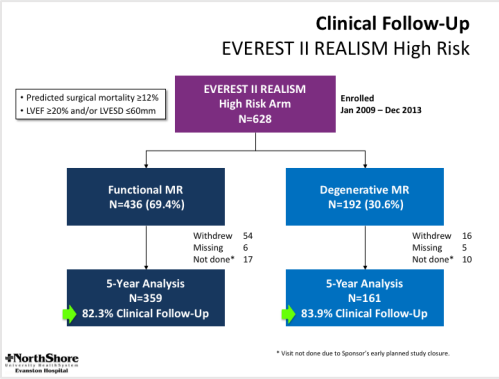


RESULTADOS CLAVE

Re-Interventions Through 5 Years

Baseline Characteristics	EVEREST II REALISM High Risk		
	All High Risk (N=628)	Functional MR (N=436)	Degenerative MR (N=192)
MV Surgery Post-Index Procedure	**25 (4.0%)**	**20 (4.6%)**	**5 (2.6%)**
Within 1 Year	18 (2.9%)	14 (3.2%)	4 (2.1%)
Between 1 Year and 5 Years	7 (1.1%)	6 (1.4%)	1 (0.5%)
Second MitraClip Device Intervention	**33 (5.3%)**	**23 (5.3%)**	**10 (5.2%)**
Within 1 Year	17 (2.7%)	12 (2.8%)	5 (2.6%)
Between 1 Year and 5 Years	16 (2.6%)	11 (2.5%)	5 (2.6%)

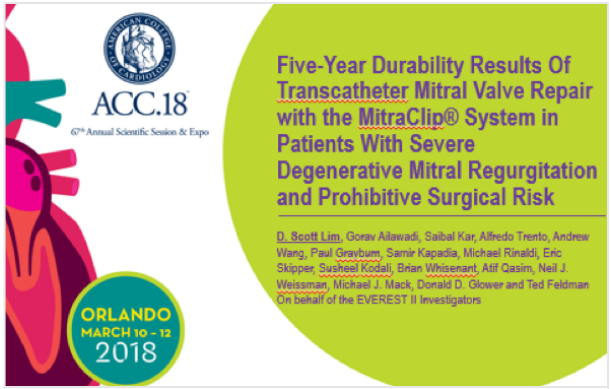
MV Surgery Type:
- 22 MV replacements
- 3 MV repairs

NorthShore University HealthSystem Evanston Hospital

- Feldman T. The EVEREST II REALISM Continued Access Study: Five Year Outcomes in High Surgical Risk Patients. Presented at EuroPCR 2018.

MitraClip en la IM: Tasa de Reintervenciones PR IM Degenerativa

DESCRIPCIÓN GENERAL DEL ESTUDIO



RESULTADOS CLAVE

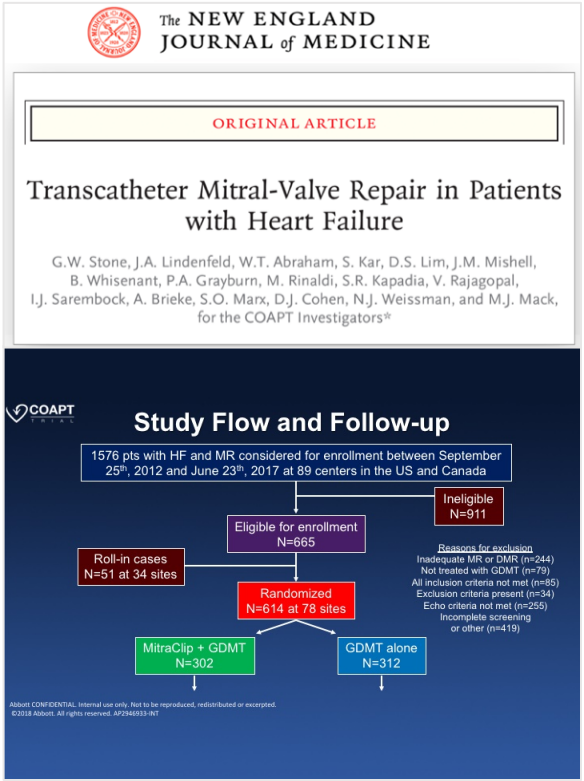
Re-Interventions Through 5 Years

Re-Intervention	# (%) of patients	Time to Re-Intervention Post-Index Procedure
MV Surgery Post-Index Procedure	4 (3.2%)	2, 26, 56, and 1,100 days
Second Intervention to Place an Additional MitraClip	3 (2.4%)	2.1, 4.2, and 4.9 years

- Lim S, Aliwadi G, Kar S, et al. Five-Year Durability Results of Transcatheter Mitral Valve Repair with the MitraClip® System in Patients With Severe Degenerative Mitral Regurgitation and Prohibitive Surgical Risk. Presented at ACC 2018.

MitraClip en la IM: Tasa de Reintervenciones COAPT

DESCRIPCIÓN GENERAL DEL ESTUDIO



The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

Transcatheter Mitral-Valve Repair in Patients with Heart Failure

G.W. Stone, J.A. Lindenfeld, W.T. Abraham, S. Kar, D.S. Lim, J.M. Mishell, B. Whisenant, P.A. Grayburn, M. Rinaldi, S.R. Kapadia, V. Rajagopal, I.J. Sarembock, A. Brieke, S.O. Marx, D.J. Cohen, N.J. Weissman, and M.J. Mack, for the COAPT Investigators*

RESULTADOS CLAVE

COAPT TRIAL

24-Month Event Rates (ii)

	MitraClip + GDMT (n=302)	GDMT alone (n=312)	HR [95% CI]	P-value
MV intervention or surgery*	4.0%	9.0%	0.61 [0.27, 1.36]	0.23
- MitraClip	3.7%	6.6%	0.99 [0.38, 2.58]	0.99
- Mitral valve surgery	0.4%	2.5%	0.14 [0.02, 1.17]	0.07
PCI or CABG	2.8%	4.3%	0.62 [0.24, 1.60]	0.32
Stroke	4.4%	5.1%	0.96 [0.42, 2.22]	0.93
Myocardial infarction	4.7%	6.5%	0.82 [0.38, 1.78]	0.62
New CRT implant	2.9%	3.3%	0.85 [0.31, 2.34]	0.75
LVAD or heart transplant	4.4%	9.5%	0.37 [0.17, 0.81]	0.01
- LVAD	3.0%	7.1%	0.34 [0.13, 0.87]	0.02
- Heart transplant	1.4%	3.6%	0.35 [0.09, 1.32]	0.12

*Unplanned. Kaplan-Meier time-to-first event rates

- Stone GW et al NEJM 2018 (DOI: 10.1056/NEJMoa1806640).
  Stone G. COAPT: A Randomized Trial of Transcatheter Mitral Valve Leaflet Approximation in Patients with Heart Failure and Secondary Mitral Regurgitation. Presented at TCT 2018.

MitraClip en la IM: Tasa de Reintervenciones TVT Registry

DESCRIPCIÓN GENERAL DEL ESTUDIO

JOURNAL OF THE AMERICAN COLLEGE OF CARDIOLOGY VOL. 70, NO. 19, 2017
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PUBLISHED BY ELSEVIER https://doi.org/10.1016/j.jacc.2017.09.015

ORIGINAL INVESTIGATIONS

Outcomes With Transcatheter Mitral Valve Repair in the United States

An STS/ACC TVT Registry Report

Paul Sorajja, MD,[a] Sreekanth Vemulapalli, MD,[b] Ted Feldman, MD,[c] Michael Mack, MD,[d] David R. Holmes, Jr, MD,[e] Amanda Stebbins, MS,[b] Saibal Kar, MD,[f] Vinod Thourani, MD,[g] Gorav Ailawadi, MD[h]

Data Analysis

- Patient characteristics, procedural, and in-hospital events sourced from TVT registry (n=2,952)
  - Acute procedural success defined as post-procedural MR ≤2, without surgery or death
- 30-day and 1-year events from linked CMS claims data (n=1,867 or 63%)
  - Examined death, MV surgery, and re-hospitalization for heart failure

STS/ACC TVT Registry™

The Society of Thoracic Surgeons | AMERICAN COLLEGE of CARDIOLOGY

RESULTADOS CLAVE

Procedural Adverse Events

TABLE 4 | 30-DAY AND 1-YEAR CLINICAL OUTCOMES

	NUMBER OF EVENTS	30 DAYS	NUMBER OF EVENTS	1 YEAR
Death	96	5.2	336	25.8
Myocardial infarction	3	0.2	27	2.5
Stroke				
Any stroke	17	1.0	36	2.7
Hemorrhagic	6	0.4	8	0.6
Heart Failure hospitalization	80	4.7	254	20.2
Mitral valve surgery	9	0.4	10	2.1
Repeat MitraClip®	23	1.3	80	6.2

Values are % unless otherwise indicated. Each variable was linked to U.S. Center for Medicare and Medicaid Services data among 1867 patients with linkage data.

- Sorajja P, Vemulapalli S, Feldman T, et al. Outcomes With Transcatheter Mitral Valve Repair in the United States: An STS/ACC TVT Registry Report. *J Am Coll Cardiol*. 2017;70(19):2315-2327.
- Sorajja P, Vemulapalli S, Feldman T, et al. Clinical Outcomes at 1-year after Commercial Transcatheter Mitral Valve Repair in the United States. Presented at ACC 2017.

FUNDACIÓN FAVALORO HOSPITAL UNIVERSITARIO

MitraClip en la IM: Tasa de Reintervenciones TRAMI

DESCRIPCIÓN GENERAL DEL ESTUDIO

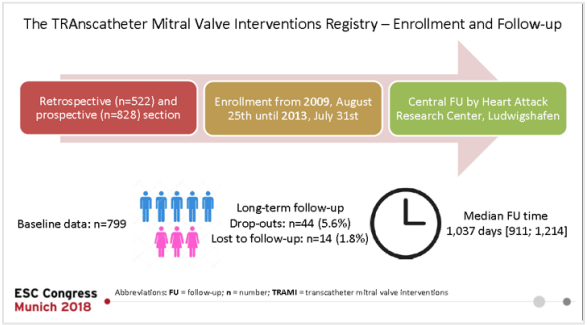
Contents lists available at ScienceDirect

International Journal of Cardiology

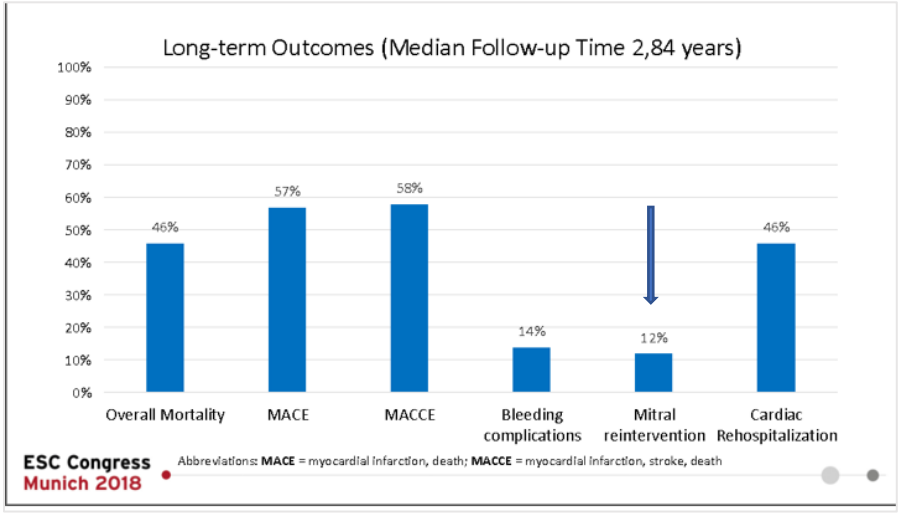
journal homepage: www.elsevier.com/locate/ijcard

Long-term outcome, survival and predictors of mortality after MitraClip therapy: Results from the German Transcatheter Mitral Valve Interventions (TRAMI) registry☆

Daniel Kalbacher [a], Ulrich Schäfer [a], R. Stephan v. Bardeleben [b], Holger Eggebrecht [c], Horst Sievert [d], Georg Nickenig [e], Christian Butter [f], Andreas E. May [g], Raffi Bekeredjian [h], Taoufik Ouarrak [i], Karl-Heinz Kuck [j], Björn Plicht [k], Ralf Zahn [l], Stephan Baldus [m], Hüseyin Ince [n], Wolfgang Schillinger [o], Peter Boekstegers [p], Jochen Senges [i], Edith Lubos [a,*]



RESULTADOS CLAVE



- Kalbacher D, Schäfer U, V Bardeleben RS, et al. Long-term outcome, survival and predictors of mortality after MitraClip therapy: Results from the German Transcatheter Mitral Valve Interventions (TRAMI) registry. *Int J Cardiol.* 2018; pii: S0167-5273(18)32310-6.
- Kalbacher D, Schäfer U, Bardeleben S, et al. Long-term follow-up in the German TRAnscatheter Mitral Valve Interventions (TRAMI) registry: survival and predictors of mortality. Presented at ESC 2018.

MitraClip en la IM:

Impacto IM Residual a Largo Plazo

MitraClip en la IM:
Impacto IM Residual en Resultados a Largo Plazo

- **Estudios**
  - EVEREST II RCT
  - PR PMR
  - STS/ACC TVT Registry

Impacto de la Insuficiencia Mitral Residual en los Resultados a Largo Plazo| EVEREST II RCT

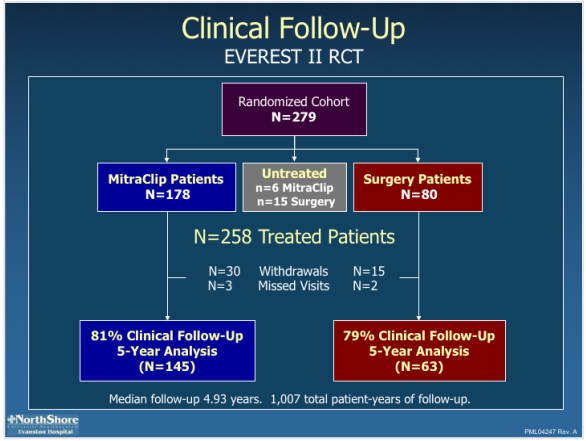
DESCRIPCIÓN GENERAL DEL ESTUDIO

JOURNAL OF THE AMERICAN COLLEGE OF CARDIOLOGY VOL. 66, NO. 25, 2015

Randomized Comparison of Percutaneous Repair and Surgery for Mitral Regurgitation

5-Year Results of EVEREST II

Ted Feldman, MD,* Saibal Kar, MD,† Sammy Elmariah, MD, MPH,‡§ Steven C. Smart, MD,* Alfredo Trento, MD,‖ Robert J. Siegel, MD,† Patricia Apruzzese, MS,§ Peter Fail, MD,¶ Michael J. Rinaldi, MD,# Richard W. Smalling, MD, PhD,** James B. Hermiller, MD,†† David Heimansohn, MD,‡‡ William A. Gray, MD,§§ Paul A. Grayburn, MD,‖‖ Michael J. Mack, MD,¶¶ D. Scott Lim, MD,## Goraw Ailawadi, MD,*** Howard C. Herrmann, MD,††† Michael A. Acker, MD,‡‡‡ Frank E. Silvestry, MD,††† Elyse Foster, MD,§§§ Andrew Wang, MD,‖‖‖ Donald D. Glower, MD,¶¶¶ Laura Mauri, MD,### for the EVEREST II Investigators



RESULTADOS CLAVE

Long-Term Durability of Clinical Success

5-Year Outcomes in Patients Who Were Alive and Free From MR 3+/4+ and MV Surgery (or Re-Operation) at 1 Year

	EVEREST II RCT Clinical Success Groups	
Outcome	MitraClip (N=97)	Surgery (N=64)
Freedom From Death at 5 Years	87%	90%
Freedom From MV Surgery (or Re-operation) at 5 Years	94%	95%
MR ≤ 2+ at 5 Years	86%	97%
MR ≤ 1+ at 5 Years	47%	92%
NYHA Class III/IV (%) Baseline → 5 Years	47% → 6%	40% → 3%
Mean Change in LVEDV From Baseline to 5 Years	-27 ml	-45 ml
Mean Change in Diastolic SLAD From Baseline to 5 Years	0.0 cm	-0.4 cm

MR, NYHA and LV data are from survivors with paired data; freedom from events data are from Kaplan-Meier estimates

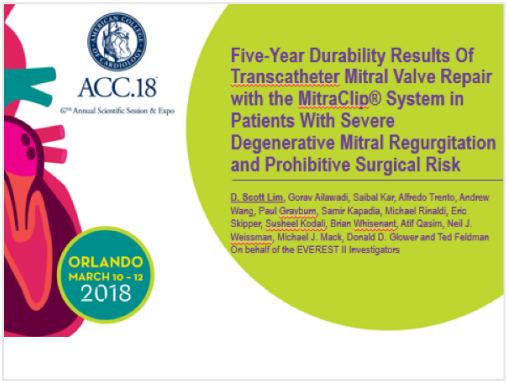
NorthShore Evanston Hospital

PML04247 Rev. A

- Feldman et al. 2015 JACC VOL.66, NO.25:2844–54
  Feldman T. Final Results of the EVEREST II Randomized Controlled Trial of Percutaneous and Surgical Reduction of Mitral Regurgitation. Presented at ACC 2014.

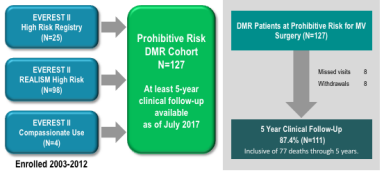
Impacto de la Insuficiencia Mitral Residual en los Resultados a Largo Plazo| PR Insuficiencia Mitral Degenerativa

DESCRIPCIÓN GENERAL DEL ESTUDIO



Methods

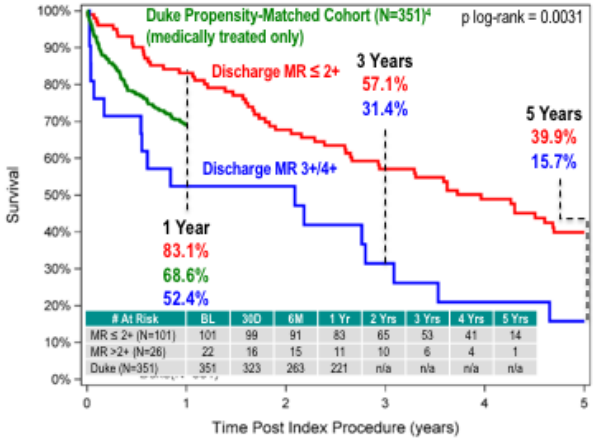
Composition of Prohibitive Risk DMR Cohort and Clinical Follow-Up



RESULTADOS CLAVE

Kaplan-Meier Freedom From All-Cause Mortality

Survival By Discharge MR Severity



PR DMR (N=127) Overall Mortality:
1 year = 75.4%
3 year = 51.0%
5 years = 34.6%

- Lim S, Aliwadi G, Kar S, et al. Five-Year Durability Results of Transcatheter Mitral Valve Repair with the MitraClip® System in Patients With Severe Degenerative Mitral Regurgitation and Prohibitive Surgical Risk. Presented at ACC 2018.

Impacto de la Insuficiencia Mitral Residual en los Resultados a Largo Plazo| TVT

DESCRIPCIÓN GENERAL DEL ESTUDIO

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STS/ACC TVT Registry

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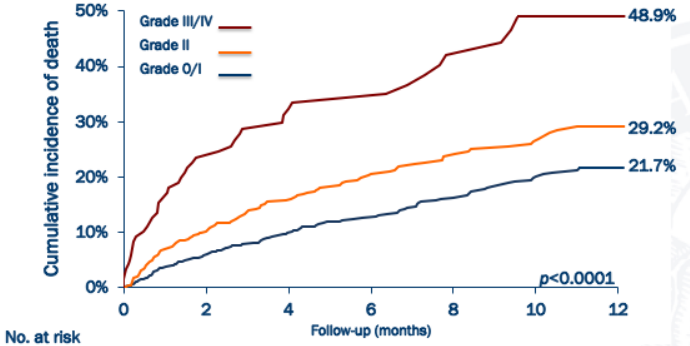
RESULTADOS CLAVE

Post-Procedural MR and Survival



STS/ACC TVT Registry

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- Sorajja P, Vemulapalli S, Feldman T, et al. Outcomes With Transcatheter Mitral Valve Repair in the United States: An STS/ACC TVT Registry Report. *J Am Coll Cardiol*. 2017;70(19):2315-2327.
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FUNDACIÓN FAVALORO HOSPITAL UNIVERSITARIO

MitraClip en la IM:

Porcentaje de Ptes con IM ≤2+ en Consulta Inicial y Seguimiento

MitraClip en la IM: Porcentaje de Pacientes con IM ≤2+ en las Consultas Iniciales y de Seguimiento| EVEREST II RCT

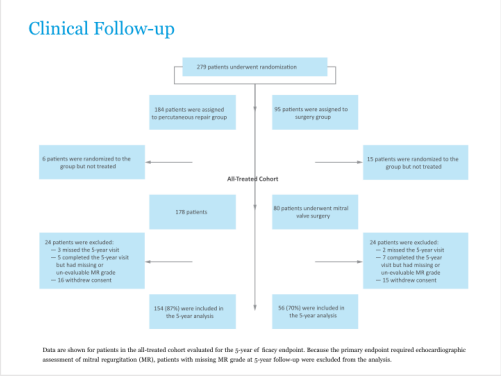
- **ESTUDIOS**
  - EVEREST II RCT
  - EVEREST II HRR
  - REALISM Continued Access Study - Non-HR
  - REALISM Continued Access Study - HR
  - PR PMR
  - Estudio COAPT
  - Estudio MITRA-FR
  - STS/ACC TVT Registry

MitraClip en la IM: Porcentaje de Pacientes con IM ≤2+ en las Consultas Iniciales y de Seguimiento| EVEREST II RCT

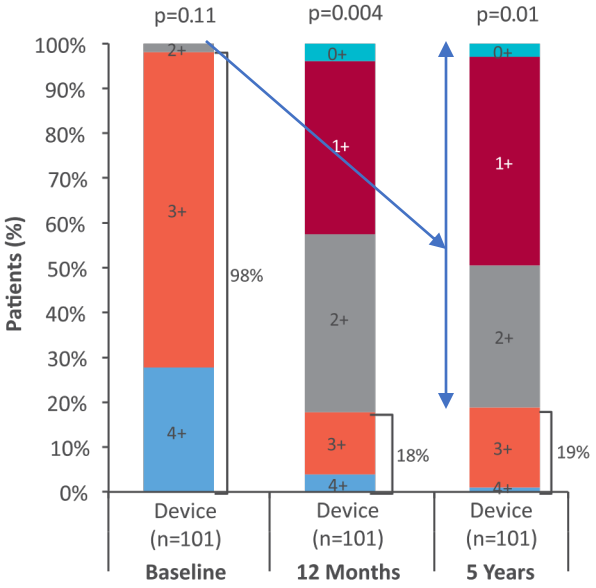
DESCRIPCIÓN GENERAL DEL ESTUDIO

Randomized Comparison of Percutaneous Repair and Surgery for Mitral Regurgitation

5-Year Results of EVEREST II



RESULTADOS CLAVE



- Feldman T, Kar S, Elmariah S, et al. Randomized Comparison of Percutaneous Repair and Surgery for Mitral Regurgitation. 5-Year Results of EVEREST II. *J Am Coll Cardiol.* 2015;66(25):2844-2854.
- Feldman T. Final Results of the EVEREST II Randomized Controlled Trial of Percutaneous and Surgical Reduction of Mitral Regurgitation. Presented at ACC 2014.

MitraClip en la IM: Porcentaje de Pacientes con IM ≤2+ en las Consultas Iniciales y de Seguimiento| EVEREST II HRR

DESCRIPCIÓN GENERAL DEL ESTUDIO

Valvular heart disease

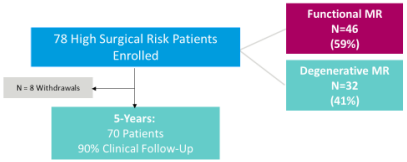
ORIGINAL RESEARCH ARTICLE

Five-year outcomes of transcatheter reduction of significant mitral regurgitation in high-surgical-risk patients

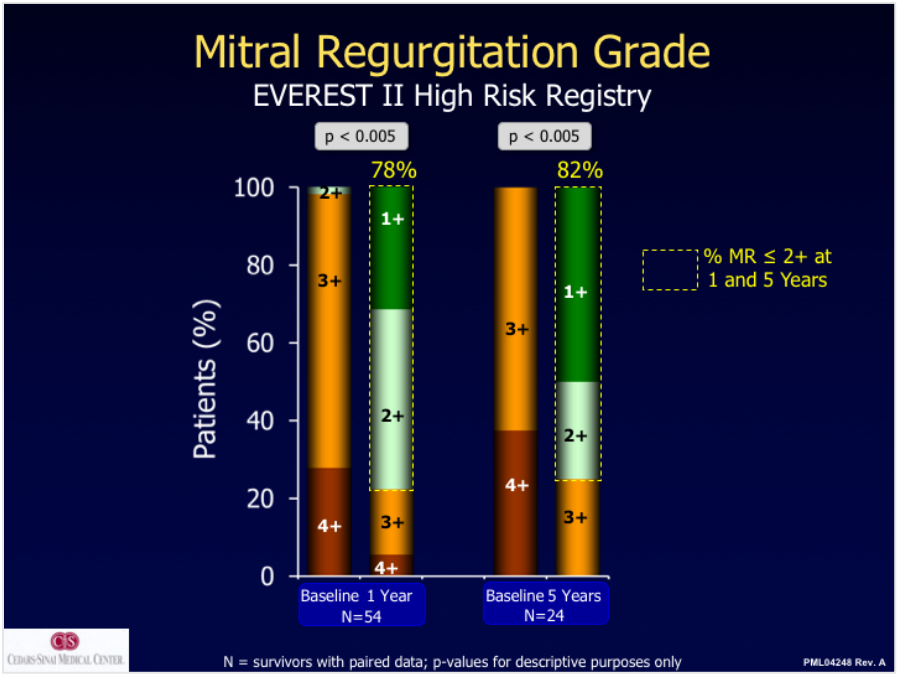
Saibal Kar,[1,2] Ted Feldman,[3] Atif Qasim,[4] Alfredo Trento,[1] Samir Kapadia,[5] Wesley Pedersen,[6] D Scott Lim,[7] Robert Kipperman,[8] Richard W Smalling,[9] Tanvir Bajwa,[10] Howard C Hermann,[11] James B Hermiller,[12] John M Lasala,[13] Mark Reisman,[14] Donald Glower,[15] Laura Mauri,[16] Patrick Whitlow,[5] on behalf of the EVEREST II Investigators

EVEREST II HRR
Study Design and Clinical Follow-up

- Symptomatic patients with significant MR (≥3+)
- Surgical risk based on a STS calculated risk score ≥12% or a surgeon estimated risk score ≥12% based on prespecified criteria
- Left ventricular function: EF>20%; LVESD<60mm
- Mitral valve anatomy suitable for the MitraClip® Device



RESULTADOS CLAVE



- Kar S, Feldman T, Qasim A, et al Five-year outcomes of transcatheter reduction of significant mitral regurgitation in high-surgical-risk patients Heart Published Online First: 04 August 2018. doi: 10.1136/heartjnl-2017-312605
- Kar S, Whitlow P, Pedersen W, et al. Effectiveness Of Transcatheter Reduction Of Significant Mitral Regurgitation In High Surgical Risk Patients With Mitraclip: Final 5 Year Results Of The EVEREST II High Risk Registry. Journal of the American College of Cardiology Apr 2014, 63 (12 Supplement) A1683; DOI: 10.1016/S0735-1097(14)61686-7. Presented at ACC 2014 - Presentation Number 2901-04.

MitraClip en la IM: Porcentaje de Pacientes con IM ≤2+ en las Consultas Iniciales y de Seguimiento| REALISM Non-HR

DESCRIPCIÓN GENERAL DEL ESTUDIO | **RESULTADOS CLAVE**

The EVEREST II REALISM Continued Access Non-High Risk Study: Mid- and Long-Term Follow-up in Surgical Candidates

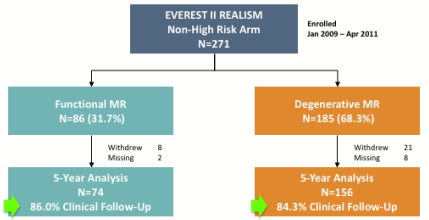
Ted Feldman MD, Saibal Kar MD, D Scott Lim MD, Richard Smalling MD, Brian Whisenant MD, Chad Rammohan MD, Peter Fail MD, Michael Rinaldi MD, James Herminller MD, Howard Herrmann MD, Robert Kipperman MD, James Slater MD, Elyse Foster MD, Neil J. Weissman MD, and Donald Glower MD
On behalf of the EVEREST II Investigators

ESC 2017
August 28, 2017

EVEREST II REALISM (NCT01931956) funded by Abbott Vascular. Investigators received research support from Abbott Vascular.

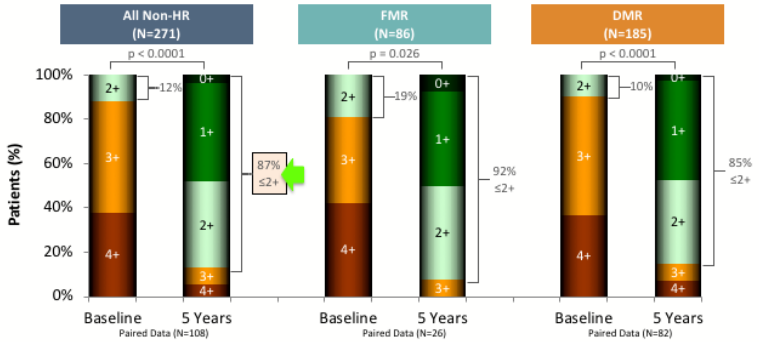
Clinical Follow-Up

EVEREST II REALISM Non-High Risk



REALISM NHRR 5-year (N=271) Mitral Regurgitation Severity to 5 Years

Echo Core Lab Assessed

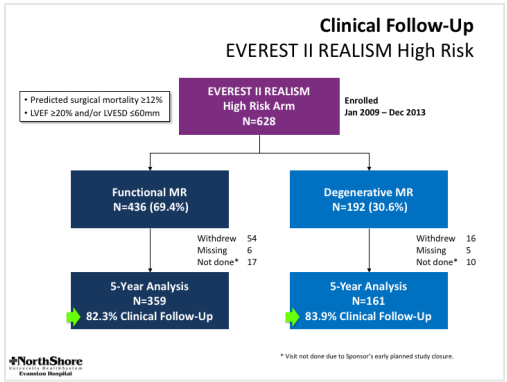


- Feldman T. The EVEREST II REALISM Continued Access Non-High Risk Study: Mid- and Long-Term Follow-up in Surgical Candidates. Presented at ESC 2017.

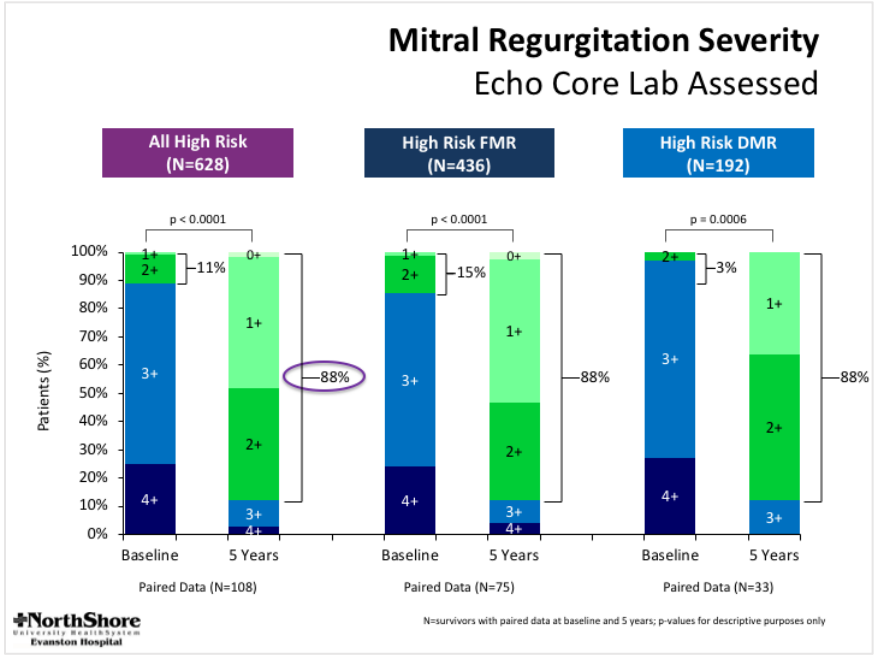
FUNDACIÓN FAVALORO HOSPITAL UNIVERSITARIO

MitraClip en la IM: Porcentaje de Pacientes con IM ≤2+ en las Consultas Iniciales y de Seguimiento| REALISM HR

DESCRIPCIÓN GENERAL DEL ESTUDIO



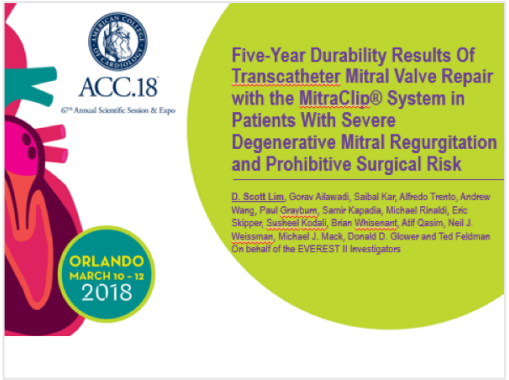
RESULTADOS CLAVE

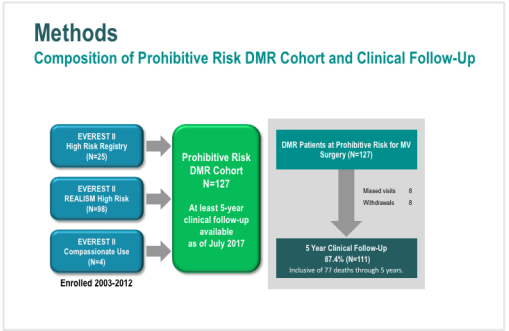


- Feldman T. The EVEREST II REALISM Continued Access Study: Five Year Outcomes in High Surgical Risk Patients. Presented at EuroPCR 2018.

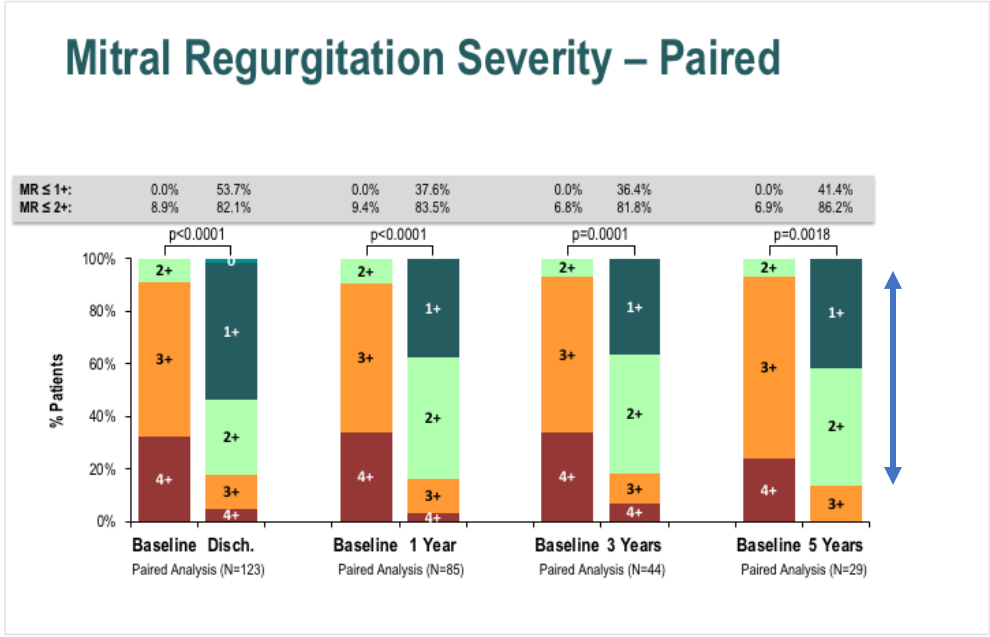
MitraClip en la IM: Porcentaje de Pacientes con IM ≤2+ en las Consultas Iniciales y de Seguimiento| IM Degenerativa

DESCRIPCIÓN GENERAL DEL ESTUDIO





RESULTADOS CLAVE



- Lim S, Aliwadi G, Kar S, et al. Five-Year Durability Results of Transcatheter Mitral Valve Repair with the MitraClip® System in Patients With Severe Degenerative Mitral Regurgitation and Prohibitive Surgical Risk. Presented at ACC 2018.

MitraClip en la IM: Porcentaje de Pacientes con IM ≤2+ en las Consultas Iniciales y de Seguimiento| COAPT

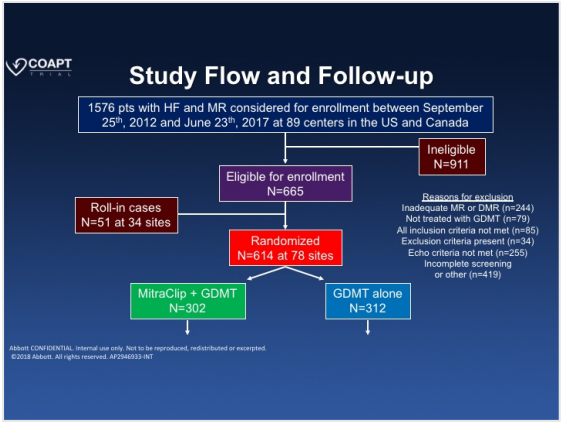
DESCRIPCIÓN GENERAL DEL ESTUDIO

The NEW ENGLAND JOURNAL of MEDICINE

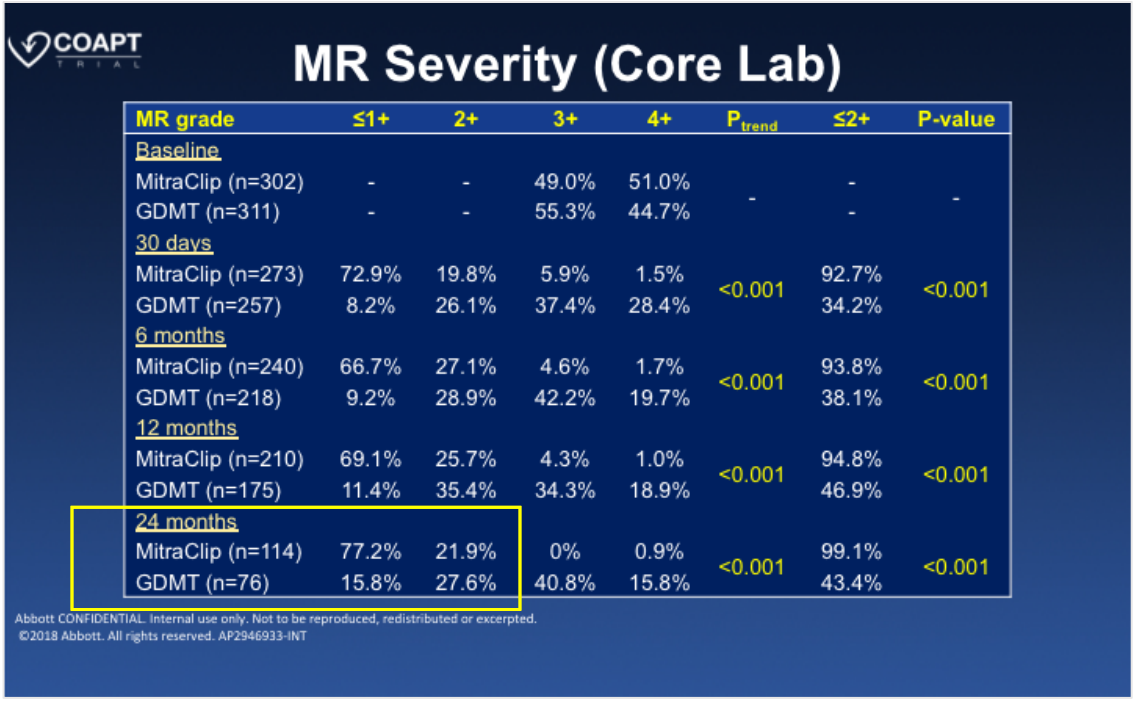
ORIGINAL ARTICLE

Transcatheter Mitral-Valve Repair in Patients with Heart Failure

G.W. Stone, J.A. Lindenfeld, W.T. Abraham, S. Kar, D.S. Lim, J.M. Mishell, B. Whisenant, P.A. Grayburn, M. Rinaldi, S.R. Kapadia, V. Rajagopal, I.J. Sarembock, A. Brieke, S.O. Marx, D.J. Cohen, N.J. Weissman, and M.J. Mack, for the COAPT Investigators*



RESULTADOS CLAVE

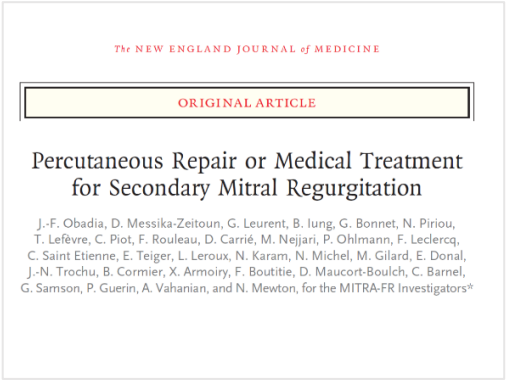


MR grade	≤1+	2+	3+	4+	P_{trend}	≤2+	P-value
Baseline							
MitraClip (n=302)	-	-	49.0%	51.0%	-	-	-
GDMT (n=311)	-	-	55.3%	44.7%		-	
30 days							
MitraClip (n=273)	72.9%	19.8%	5.9%	1.5%	<0.001	92.7%	<0.001
GDMT (n=257)	8.2%	26.1%	37.4%	28.4%		34.2%	
6 months							
MitraClip (n=240)	66.7%	27.1%	4.6%	1.7%	<0.001	93.8%	<0.001
GDMT (n=218)	9.2%	28.9%	42.2%	19.7%		38.1%	
12 months							
MitraClip (n=210)	69.1%	25.7%	4.3%	1.0%	<0.001	94.8%	<0.001
GDMT (n=175)	11.4%	35.4%	34.3%	18.9%		46.9%	
24 months							
MitraClip (n=114)	77.2%	21.9%	0%	0.9%	<0.001	99.1%	<0.001
GDMT (n=76)	15.8%	27.6%	40.8%	15.8%		43.4%	

- Stone GW et al NEJM 2018 (DOI: 10.1056/NEJMoa1806640).
  Stone G W, Lindenfeld J, Abraham WT, et al. Transcatheter Mitral-Valve Repair in Patients with Heart Failure. *N Engl J Med*. 2018.

MitraClip en la IM: Porcentaje de Pacientes con IM ≤2+ en las Consultas Iniciales y de Seguimiento| MITRA-FR

DESCRIPCIÓN GENERAL DEL ESTUDIO | **RESULTADOS CLAVE**

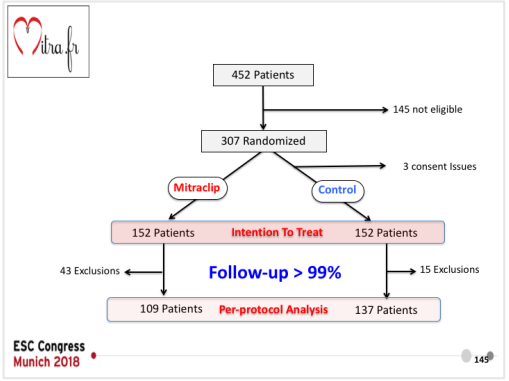


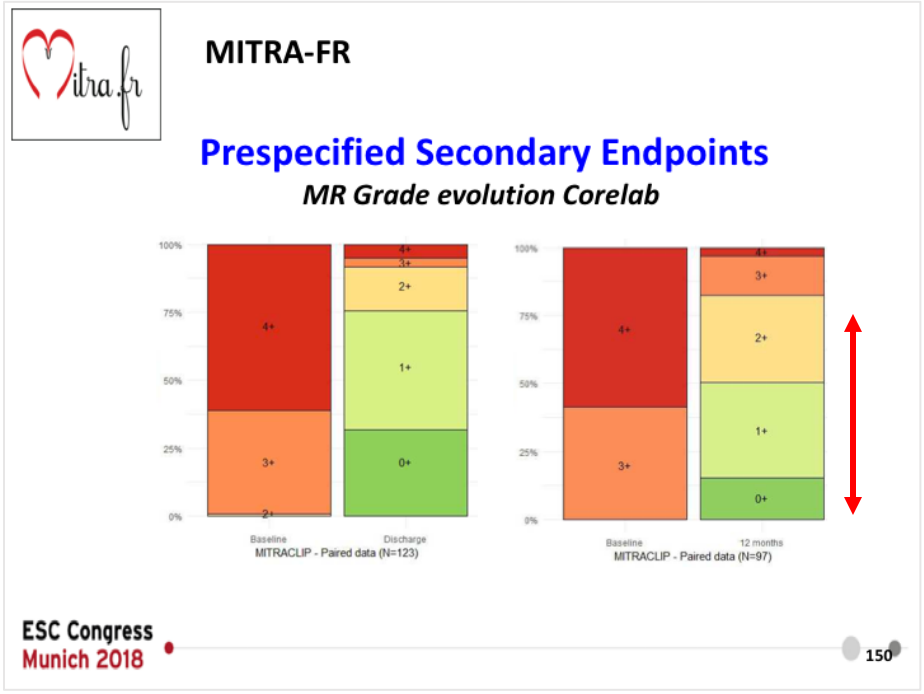
The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

Percutaneous Repair or Medical Treatment for Secondary Mitral Regurgitation

J.-F. Obadia, D. Messika-Zeitoun, G. Leurent, B. Iung, G. Bonnet, N. Piriou, T. Lefèvre, C. Piot, F. Rouleau, D. Carrié, M. Nejjari, P. Ohlmann, F. Leclercq, C. Saint Etienne, E. Teiger, L. Leroux, N. Karam, N. Michel, M. Gilard, E. Donal, J.-N. Trochu, B. Cormier, X. Armoiry, F. Boutitie, D. Maucort-Boulch, C. Barnel, G. Samson, P. Guerin, A. Vahanian, and N. Mewton, for the MITRA-FR Investigators*





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MitraClip en la IM: Porcentaje de Pacientes con IM ≤2+ en las Consultas Iniciales y de Seguimiento| TVT

DESCRIPCIÓN GENERAL DEL ESTUDIO

JOURNAL OF THE AMERICAN COLLEGE OF CARDIOLOGY VOL. 70, NO. 19, 2017
© 2017 BY THE AMERICAN COLLEGE OF CARDIOLOGY FOUNDATION ISSN 0735-1097/$36.00
PUBLISHED BY ELSEVIER https://doi.org/10.1016/j.jacc.2017.09.015

ORIGINAL INVESTIGATIONS

Outcomes With Transcatheter Mitral Valve Repair in the United States

An STS/ACC TVT Registry Report

Paul Sorajja, MD,[a] Sreekanth Vemulapalli, MD,[b] Ted Feldman, MD,[c] Michael Mack, MD,[d] David R. Holmes, Jr, MD,[e] Amanda Stebbins, MS,[b] Saibal Kar, MD,[f] Vinod Thourani, MD,[g] Gorav Ailawadi, MD[g]

Data Analysis

- Patient characteristics, procedural, and in-hospital events sourced from TVT registry (n=2,952)
  - Acute procedural success defined as post-procedural MR ≤2, without surgery or death
- 30-day and 1-year events from linked CMS claims data (n=1,867 or 63%)
  - Examined death, MV surgery, and re-hospitalization for heart failure

STS/ACC TVT Registry

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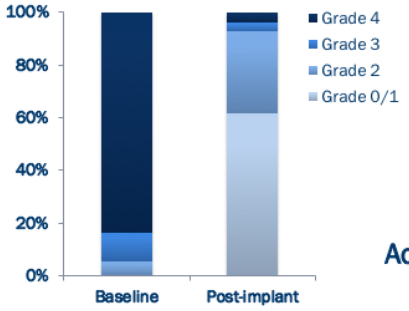
RESULTADOS CLAVE

TVT Registry

Acute Procedural Results



92.8% with post-procedural MR ≤2

SLDA, 1.5%

In-hospital mortality = 2.7%

85.9% discharged home

Median LOS, 2 days (1, 5 days)

Acute procedure success = 91.8%

STS/ACC TVT Registry

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- Sorajja P, Vemulapalli S, Feldman T, et al. Outcomes With Transcatheter Mitral Valve Repair in the United States: An STS/ACC TVT Registry Report. *J Am Coll Cardiol*. 2017;70(19):2315-2327
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FUNDACIÓN FAVALORO HOSPITAL UNIVERSITARIO

Aspectos para que el Programa Funcione Más Allá de la Barrera Económica

- Conocer la evidencia que lo soporta aunque no sea tan abrumadora como TAVI
- Formar un Team
- Tener un grupo dedicado a IC
- Tener equipos adecuados y personal especializado en imágenes
- Entrenar el equipo de Intervencionistas, Muy pocos y con volumen.

Aspectos para que el Programa Funcione Más Allá de la Barrera Económica

Rogar que este país no desaparezca