

Transición hacia Cirugía Coronaria sin CEC con excelentes resultados

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Morbidities Associated With CPB

- Myocardial Necrosis
- Systemic Inflammatory Response
- Neuro-Cog effects / Brain injury
- Pump Lung (Adult Respiratory Distress Syndrome)
- Hypertension and distention of the heart
- Renal Dysfunction
- Embolization
- Coagulation Disorders
- Increased Blood Loss



La Cirugia Coronaria sin Circulacion Extracorporea:

- *Por que ?*
 - *Cuales son los beneficios ?*
 - *Cuales son las desventajas ?*
 - *Que pacientes se benefician mas ?*
- *Como implementamos nuestro programa ?*
- *Que resultados obtuvimos ?*



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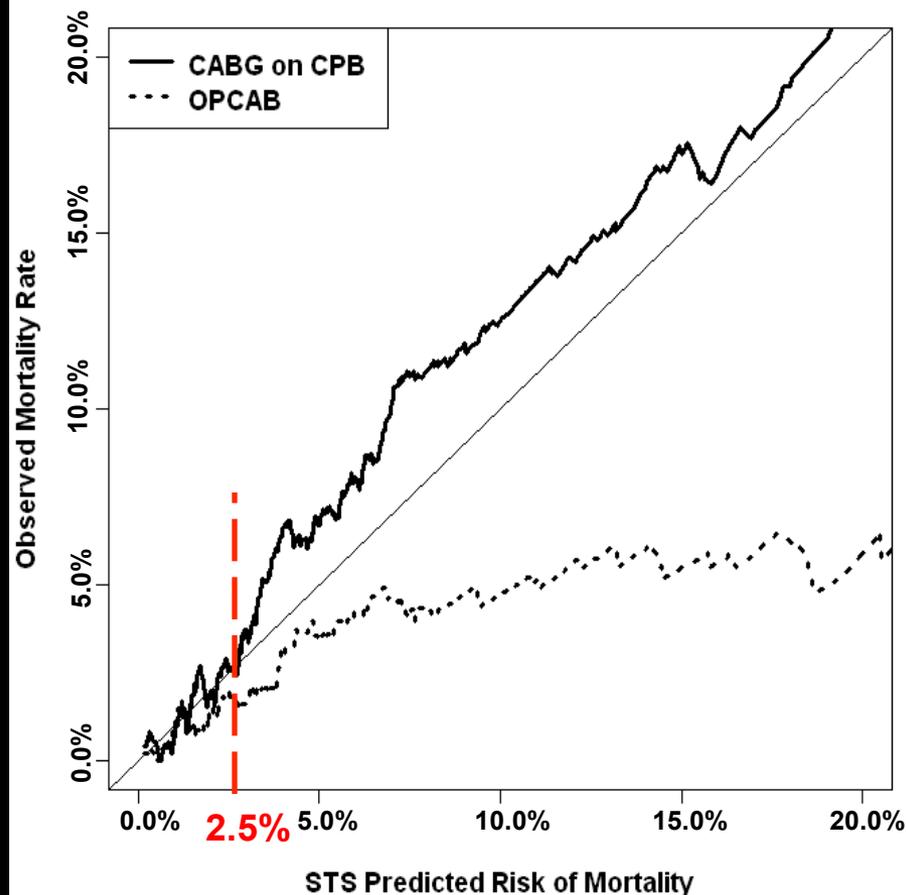


A Mayor Riego, Menor Mortalidad con CRM Sin CEC

STS 2009: Puskas y col.

- Retrospective study performed by querying the STS database
- 14,766 consecutive CABG patients at Emory performed by 17 surgeons.
- Analyzed in 4 quartiles stratified by risk, as defined by the STS PROM equation
- OPCAB significantly reduced 30-day mortality vs. conventional CABG in the highest risk group (> 2.5% PROM)

PROM Range	OPCAB Deaths (%)	CAB Deaths (%)	OPCAB Odds Ratio (95% CI)	p-value
0%-0.75%	5/1824 (0.3)	6/1883 (0.3)	0.86 (0.26, 2.82)	0.80
0.75%-1.3%	15/1755 (0.9)	17/1921 (0.9)	0.97 (0.48, 1.94)	0.92
1.3%-2.5%	19/1665 (1.1)	37/2025 (1.8)	0.62 (0.36, 1.08)	0.09
>2.5%	58/1839 C(3.2)	124/1854 (6.7)	0.45 (0.33, 0.63)	<0.0001



Puskas y col. Ann Thorac Surg 2009

Mortalidad en Grupos de alto Riesgo

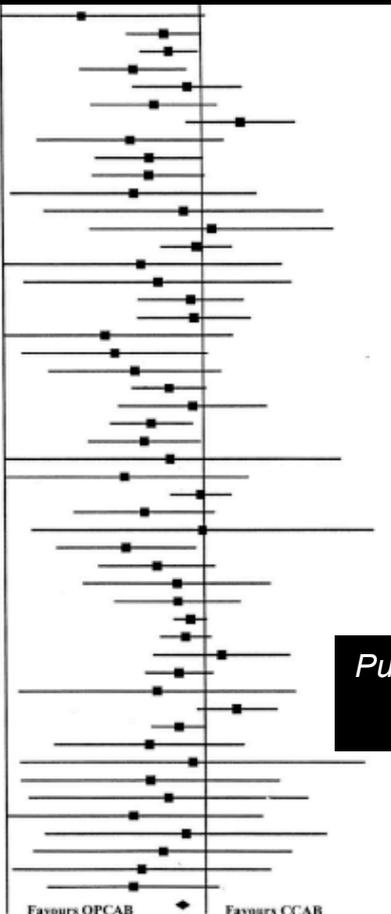
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Death: OPCAB vs CCAB for High Risk Gro

Sin CEC – Con CEC

RiskGroups	Citation	Treated	Control	Effect	Lower	Upper	PValue
Diabetic	Abraham 01 (Diab)	10 / 254	34 / 973	1.13	.55	2.32	.74
Elderly	Al Ruzzeh 01 (age)	0 / 56	10 / 87	.07	.00	1.14	.01
LVDysfunction	Al Ruzzeh 03 (LVD)	7 / 106	28 / 199	.43	.18	1.02	.05
EuroscoreParsonnetHigh	AlRuzzh EJCS 03 (Euro5)	10 / 286	78 / 1112	.48	.25	.94	.03
Multirisks	Arom 00 (multirisk)	3 / 39	35 / 123	.21	.06	.72	.01
RenalDysfunction	Ascione 01 (RF)	3 / 51	16 / 202	.73	.20	2.60	.62
Multirisks	Ascione 02 (obese)	2 / 674	19 / 2170	.34	.08	1.46	.13
LVDysfunction	Ascione			.8	.70	8.83	.15
Multirisks	Balkhy			.9	.02	1.67	.10
RenalDysfunction	Beaufe			.0	.09	1.04	.05
EuroscoreParsonnetHigh	Bellef			.9	.08	1.08	.05
EuroscoreParsonnetHigh	Boyd 0			.1	.01	3.55	.23
Elderly	Boyd 9			.5	.03	16.44	.79
Multirisks	Carrier			.5	.07	20.89	.88
Multirisks	Chmbr			.7	.38	1.99	.74
COPD	Covino			.4	.01	6.30	.36
RedoEmergentCABG	Czemy			.5	.02	7.87	.50
Elderly	Demier			.5	.22	2.59	.65
Elderly	Deuse			.2	.22	3.06	.76
LVDysfunction	Deuse			.0	.01	2.01	.07
Multirisks	Deuse			.3	.02	1.12	.03
LeftMainDisease	Dewey			.0	.03	1.51	.09
LVDysfunction	Dewey			.5	.19	1.07	.06
AtheroscleroticAorta	Gaidir			.8	.14	4.36	.78
EuroscoreParsonnetHigh	Gaudino 04 (Euro5)	7 / 197	12 / 109	.30	.11	.78	.01
LVDysfunction	Goldstein 03 (LVD)	3 / 100	12 / 110	.25	.07	.92	.03
COPD	Guler 01 (COPD)	0 / 40	0 / 18	.46	.01	23.92	.69
Elderly	Hoff 02 (Age80)	0 / 69	8 / 169	.16	.01	2.81	.16
RedoEmergentCABG	Karthik 02 (emerg)	15 / 417	16 / 411	.92	.45	1.89	.82
RedoEmergentCABG	Kilo 01 (age75, emerg)	2 / 44	7 / 44	.25	.05	1.29	.06
LVDysfunction	Kirali 02 (LVD)	0 / 26	0 / 25	.96	.02	50.35	.98
RedoEmergentCABG	Locker 00 (emerg)	2 / 40	9 / 37	.16	.00	.82	.02
Elderly	Martinovic 03 (age80)	3 / 68	9 / 74	.33	.09	1.29	.10
EuroscoreParsonnetHigh	McKay 01 (Parsonnet-9)	1 / 10	10 / 58	.53	.06	4.70	.57
LeftMainDisease	Meharwal 01 (Left Main)	2 / 174	21 / 991	.54	.12	2.31	.40
Multirisks	Meharwal 02 (multirisk)	35 / 1075	104 / 2312	.71	.48	1.06	.09
LVDysfunction	Meharwal HSF 02 (LVD)	14 / 355	58 / 959	.64	.35	1.16	.14
RedoEmergentCABG	Ochi 03 (Emerg)	3 / 25	4 / 47	1.47	.30	7.14	.63
Multirisks	Petro 00 (women)	7 / 304	83 / 1527	.55	.25	1.21	.13
Multirisks	Pompilio 99 (multiriskcor)	0 / 71	1 / 71	.33	.01	8.21	.48
Elderly	Ricci 00 (age80)	10 / 97	9 / 172	2.08	.82	5.32	.12
AtheroscleroticAorta	Sharoni 04 (calc aorta)	16 / 245	28 / 245	.54	.29	1.03	.06
LVDysfunction	Shennib 02 (LVD)	1 / 31	5 / 46	.27	.03	2.46	.22
RenalDysfunction	Tashiro 02 (ESRD)	0 / 15	0 / 11	.74	.01	40.24	.88
Elderly	YokoyBaum 00 (ageCVAcopdLVDredoRF)	0 / 28	3 / 58	.28	.01	5.57	.37
COPD	YokoyBaum 00 (ageCVAcopdLVDredoRF)	0 / 33	1 / 43	.42	.02	10.72	.59
AtheroscleroticAorta	YokoyBaum 00 (ageCVAcopdLVDredoRF)	0 / 25	3 / 36	.16	.01	3.80	.23
LVDysfunction	YokoyBaum 00 (ageCVAcopdLVDredoRF)	0 / 13	1 / 26	.63	.02	16.53	.78
RedoEmergentCABG	YokoyBaum 00 (ageCVAcopdLVDredoRF)	0 / 28	3 / 76	.37	.02	7.36	.50
RenalDysfunction	YokoyBaum 00 (ageCVAcopdLVDredoRF)	0 / 27	3 / 46	.23	.01	4.55	.29
Diabetic	Zapolski 03 (Diab)	1 / 142	41 / 1109	.18	.03	1.35	.06
Fixed	Combined (51)	195 / 6865	844 / 18124	.58	.49	.68	.00

Meta analisis
30.000 Pacientes
40 RCT
44 No RCT



Puskas y col. Innov CT Surg 2005

Figure 3. a-i Meta-Analysis of Clinical Outcomes for OPCAB versus CCAB in High Risk Patients (30-day death, stroke, myocardial infarction, atrial fibrillation, transfusions, renal dysfunction, inotropes, IABP, and reoperation for bleeding) [Level B/A]. (Continues)

Meta-analisis: Reston y col.

(Basado en 53 estudios / 46.621 pacientes)

Meta-Analysis of Short-Term and Mid-Term Outcomes Following Off-Pump Coronary Artery Bypass Grafting

James T. Reston, PhD, MPH, Stephen J. Tregear, PhD, and Charles M. Turkelson, PhD
Department of Health Technology Assessment, ECRI, Plymouth Meeting, Pennsylvania

Background. Uncertainty continues to surround the relative benefits and harms of conventional coronary artery bypass grafting (CABG) and off-pump coronary artery bypass grafting (OPCABG). Possible reasons are that high-quality studies have not comprehensively examined relevant patient outcomes and have enrolled a limited range of patients. Some studies may have been too small to detect clinically important differences in patient outcomes. The present study addresses these issues using meta-analysis.

Methods. We comprehensively retrieved randomized and nonrandomized controlled studies according to predetermined criteria. We performed meta-analyses for each outcome and empirically determined whether potential biases that might result from differences in study design or patient characteristics actually biased a study's results. We also conducted sensitivity analyses and tested for publication bias.

Results. Rates of perioperative myocardial infarction, stroke, reoperation for bleeding, renal failure, and mor-

tality were lower after OPCABG than after CABG. Reductions in length of hospital stay, atrial fibrillation, and wound infection were also associated with OPCABG, but statistically significant differences among study results for these outcomes could not be explained by available information. Midterm (3 to 25 months) angina recurrence did not appear to differ between treatments; a trend was noticed toward lower reintervention rates with CABG, and a trend toward lower overall mortality with OPCABG, at least when performed at experienced centers. These midterm outcome results require confirmation.

Conclusions. Off-pump coronary artery bypass grafting appears to reduce length of hospital stay, operative morbidity, and operative mortality relative to on-pump CABG. More studies are required before firm conclusions can be drawn concerning the effect of OPCABG on midterm mortality, angina recurrence, and repeat intervention.

(Ann Thorac Surg 2003;76:1510-5)

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Off-pump coronary artery bypass grafting (OPCABG) is increasingly being used as an alternative to conventional CABG with cardiopulmonary bypass. Despite this practice and the fact that a few randomized controlled trials (RCTs) have compared these procedures, uncertainty remains concerning their relative benefits and harms [1-3]. Possible reasons for this uncertainty are that existing RCTs have not comprehensively studied all relevant patient outcomes, have enrolled a limited range of patients, and some may have been too small to detect clinically important differences. The potential for publication bias (nonpublication of studies that find no statistically significant difference between OPCABG and CABG), and the fact that most of the published data are from retrospective studies, further compound the difficulties in comparing these two procedures.

We used a series of meta-analyses to address two main issues. First, meta-analysis provides additional statistical power to overcome the problem that most published studies may have been too small to find statistically

significant differences for some outcomes, particularly those that are relatively uncommon (eg, stroke). We also used meta-analysis to determine empirically whether differences in study design or quality may have resulted from biases in studies of less rigorous design. If we found evidence for bias due to study design, we based our results only on the studies of "superior" design (eg, randomized or prospective trials). If no evidence of bias was found, we included all studies in the meta-analysis.

Although some investigators include all off-pump procedures under the term OPCABG, in this report we consider OPCABG to include only those off-pump procedures performed through a full median sternotomy. We did not evaluate minimally invasive direct off-pump coronary artery bypass grafting performed through a thoracotomy or alternative small incisions (commonly referred to as MIDCABG).

Material and Methods

Study Selection

We included studies in our analysis only if they met certain a priori inclusion criteria. They had to be controlled studies that compared OPCABG and CABG; they

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Mejor sin Bomba:

- Menor Mortalidad
- Menor incidencia de
 - Stroke
 - MI Post Operatorio
 - Fib .Auricular
 - Reop. Sangrado
 - Insuf. Renal

Meta-analysis: Cheng y col.

(Basado en 37 estudios randomized 3.369 pacientes)

Mejor sin Bomba en cuanto a:

- Fib. Auricular
- Infec. Respiratorias
- Uso de Intropicos
- Transfusiones
- Tiempo de Ventilacion
- Tiempo en Recuperacion
- Estadia Hospitalaria

REVIEW ARTICLES

David C. Wartler, M.D., Ph.D., Editor

Anesthesiology 2005, 102:188-205

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Does Off-pump Coronary Artery Bypass Reduce Mortality, Morbidity, and Resource Utilization When Compared with Conventional Coronary Artery Bypass? A Meta-analysis of Randomized Trials

Dary C. Cheng, M.D., M.Sc., F.R.C.P.C.,* Daniel Bainbridge, M.D., F.R.C.P.C.,† Janet E. Martin, Pharm.D.,‡ Richard J. Novick, M.D., M.Sc., F.R.C.S.C.,§ The Evidence-based Perioperative Clinical Outcomes Research Group||

CME This article and its accompanying editorial have been selected for the Anesthesiology CME Program. After reading both articles, go to <http://www.asahq.org/journal-cme> to take the test and apply for Category 1 credit. Complete instructions may be found in the CME section at the back of this issue.

The authors undertook a meta-analysis of 37 randomized trials (3369 patients) of off-pump coronary artery bypass surgery versus conventional coronary artery bypass surgery. No significant differences were found for 30-day mortality (odds ratio [OR], 1.02; 95% confidence interval [CI], 0.58–1.80), myocardial infarction (OR, 0.77; 95% CI, 0.48–1.26), stroke (OR, 0.68; 95% CI, 0.33–1.40), renal dysfunction, intraaortic balloon pump, wound infection, rethoracotomy, or reintervention. However,

off-pump coronary artery bypass surgery significantly decreased atrial fibrillation (OR, 0.58; 95% CI, 0.44–0.77), transfusion (OR, 0.43; 95% CI, 0.29–0.65), inotropic requirements (OR, 0.48; 95% CI, 0.32–0.73), respiratory infections (OR, 0.41; 95% CI, 0.23–0.74), ventilation time (weighted mean difference, –3.4 h; 95% CI, –5.1 to –1.7 h), intensive care unit stay (weighted mean difference, –0.3 days; 95% CI –0.6 to –0.1 days), and hospital stay (weighted mean difference, –1.0 days; 95% CI –1.5 to –0.5 days). Patency and neurocognitive function results were inconclusive. In-hospital and 1-yr direct costs were generally higher for conventional coronary artery bypass surgery versus off-pump coronary artery bypass surgery. Therefore, this meta-analysis demonstrates that mortality, stroke, myocardial infarction, and renal failure were not reduced in off-pump coronary artery bypass surgery; however, selected short-term and mid-term clinical and resource outcomes were improved compared with conventional coronary artery bypass surgery.

This article is accompanied by an Editorial View. Please see: Floyd T. Reichert: LA Off-pump coronary artery bypass and the hypothesis from which it grew: Is it yet to be tested? What are the downsides of the lingering questions? ANESTHESIOLOGY 2005; 102:3-5.

Additional material related to this article can be found on the ANESTHESIOLOGY Web site. Go to <http://www.anesthesiology.org>, click on Enhancements Index, and then scroll down to find the appropriate article and link. Supplementary material can also be accessed on the Web by clicking on the "ArticlePlus" link either in the Table of Contents or at the top of the Abstract or HTML version of the article.

* Professor and Chair, † Assistant Professor, Department of Anesthesia & Perioperative Medicine, ‡ Lecturer, Department of Pharmacy, Physiology & Pharmacology, § Professor and Chair, Division of Cardiac Surgery, London Health Sciences Centre, University of Western Ontario, London, Ontario, Canada; || the members of this Research Group are listed in the Web site enhancement.

Received from the Department of Anesthesia & Perioperative Medicine, University of Western Ontario, London, Ontario, Canada, submitted for publication May 5, 2004. Accepted for publication July 16, 2004. Support was provided solely from institutional and/or departmental sources. Presented at the 25th Annual Meeting of the Society of Cardiovascular Anesthesiologists, Miami, Florida, April 26–30, 2005.

Address reprint requests to Dr. Cheng, Department of Anesthesia & Perioperative Medicine, London Health Sciences Centre-University Campus, 339 Windermere Road, Room 3-219, London, Ontario, Canada N6A 5A5. Address electronic mail to: dary.cheng@lhsc.on.ca.

Anesthesiology, V 102, No 1, Jan 2005

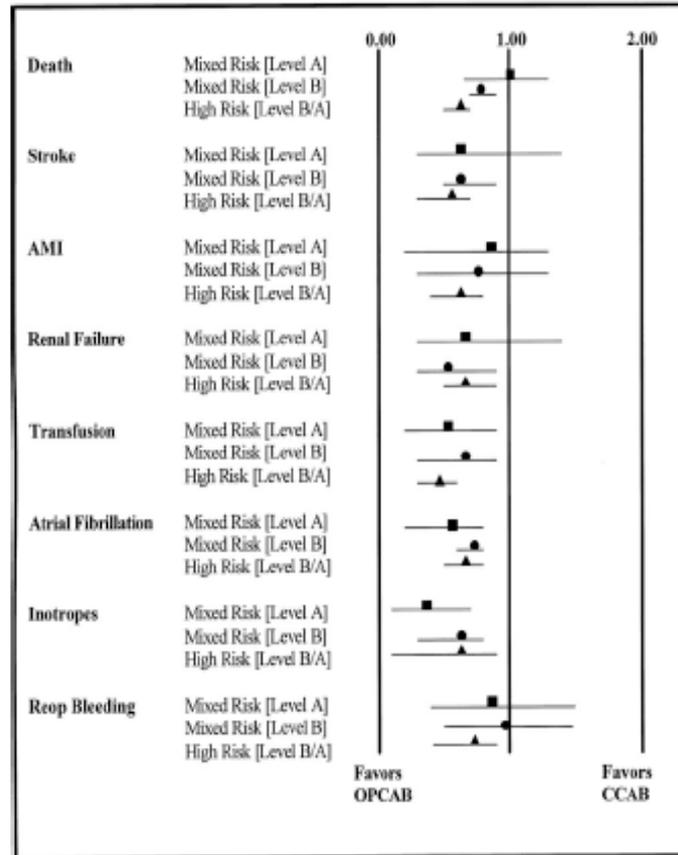
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Resumen. Puskas et al.

Meta analisis
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40 RCT
44 No RCT

Comparison of Pooled Outcomes for Mixed-Risk and High-Risk Patients



Mixed-Risk Patients [Level A] = Cheng 2004 (37 randomized trials; 3369 patients)
 Mixed-Risk Patients [Level B] = Beattie 2004 (13 non-randomized trials; 198,204 patients) or
 Reston 2003 (53 trials; 46,621 patients)
 High-Risk patients [Level B/A] = ISMICS Consensus Meta-Analysis 2004 (42 non-randomized
 trials and 3 randomized trials; 76,349 patients)

Puskas y col. Innov CT Surg 2005

Figure 5. Comparison of Pooled Outcomes for Mixed-Risk and High-Risk Patients [Level A and Level B].



Resultados Comparativos CRM con y sin CEC

- Mortalidad: 30 dias y alejada
- Calidad de Revascularizacion: Completa y permeabilidad de los injertos
- Complicaciones perioperatorias
- Funcion neurocognitiva
- Calidad de vida
- Utilizacion de recursos
- Analisis de grupos de alto riesgo

Puskas y col. Innovations in CT Surg 2005



Resultados Comparativos CRM con y sin CEC

- Mortalidad: 30 días y alejada
- Calidad de Revascularización: Completa y permeabilidad de los injertos *

* *En manos experimentadas*

- Complicaciones perioperatorias
- Funcion neurocognitiva
- Calidad de vida

**Resultados
Equivalentes**

- Utilización de recursos
- Analisis de grupos de alto riesgo

Puskas et al. Innovations in CT Surg 2005



Resultados Comparativos CRM con y sin CEC

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Mejor
sin Bomba

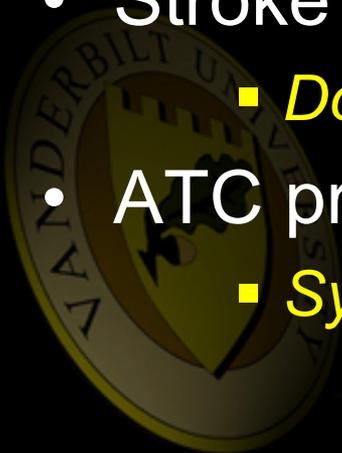
Puskas et al. Innovations in CT Surg 2005



Características

Nashville VA Medical Center

- Diabetes y Tabaquismo actual (49% y 42%)
 - *Doble que en Syntax*
- EPOC (21%)
 - *Doble que en Puskas*
- Enfermedad Vascular Periferica (36%)
 - *20% (absoluto) mayor que en ROOBY y Puskas*
- Stroke previo (12%)
 - *Doble que en Syntax. 12 veces mayor que Puskas*
- ATC previa (32%)
 - *Syntax y Rooby= 0. Comparable con Puskas*



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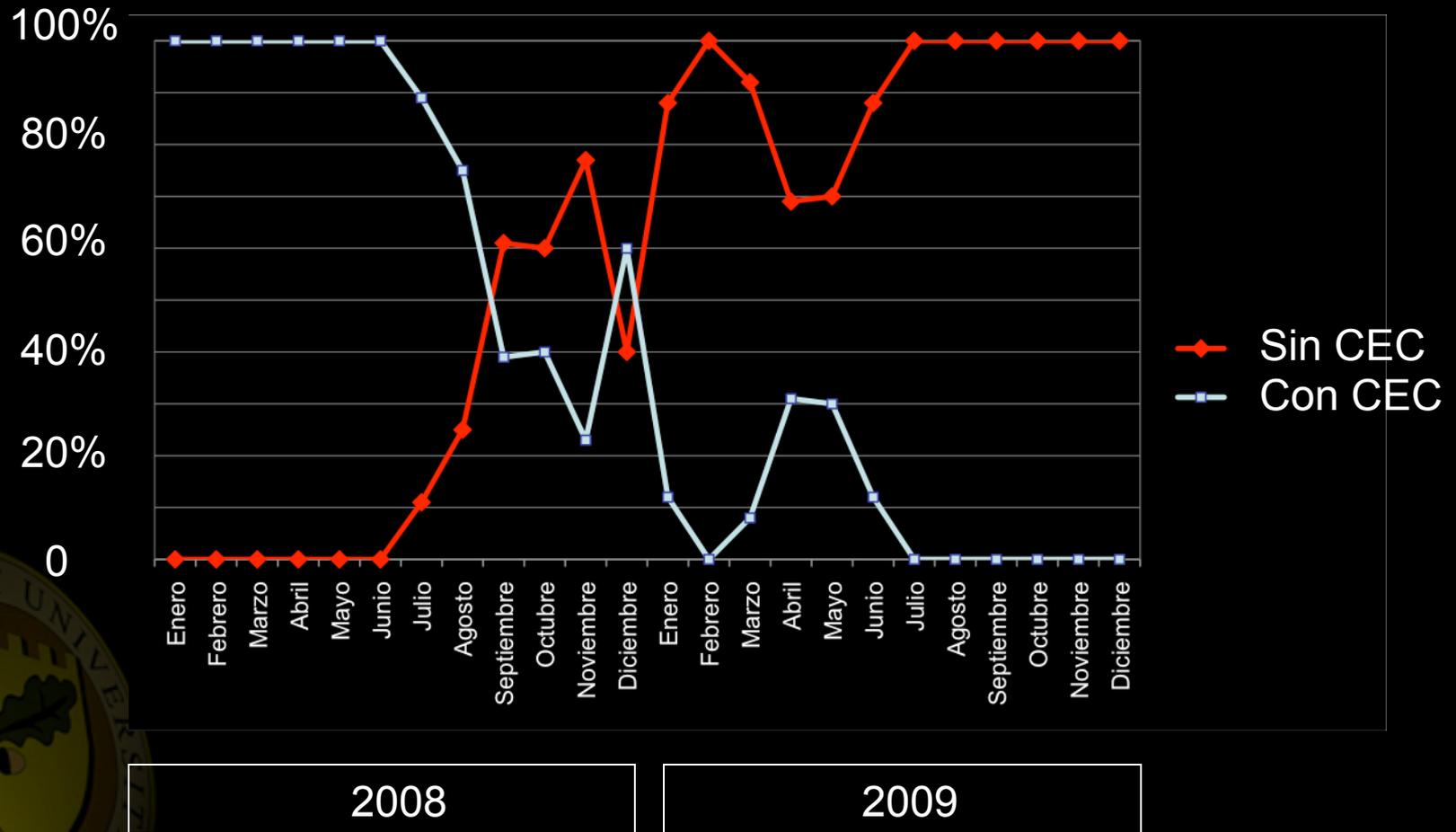


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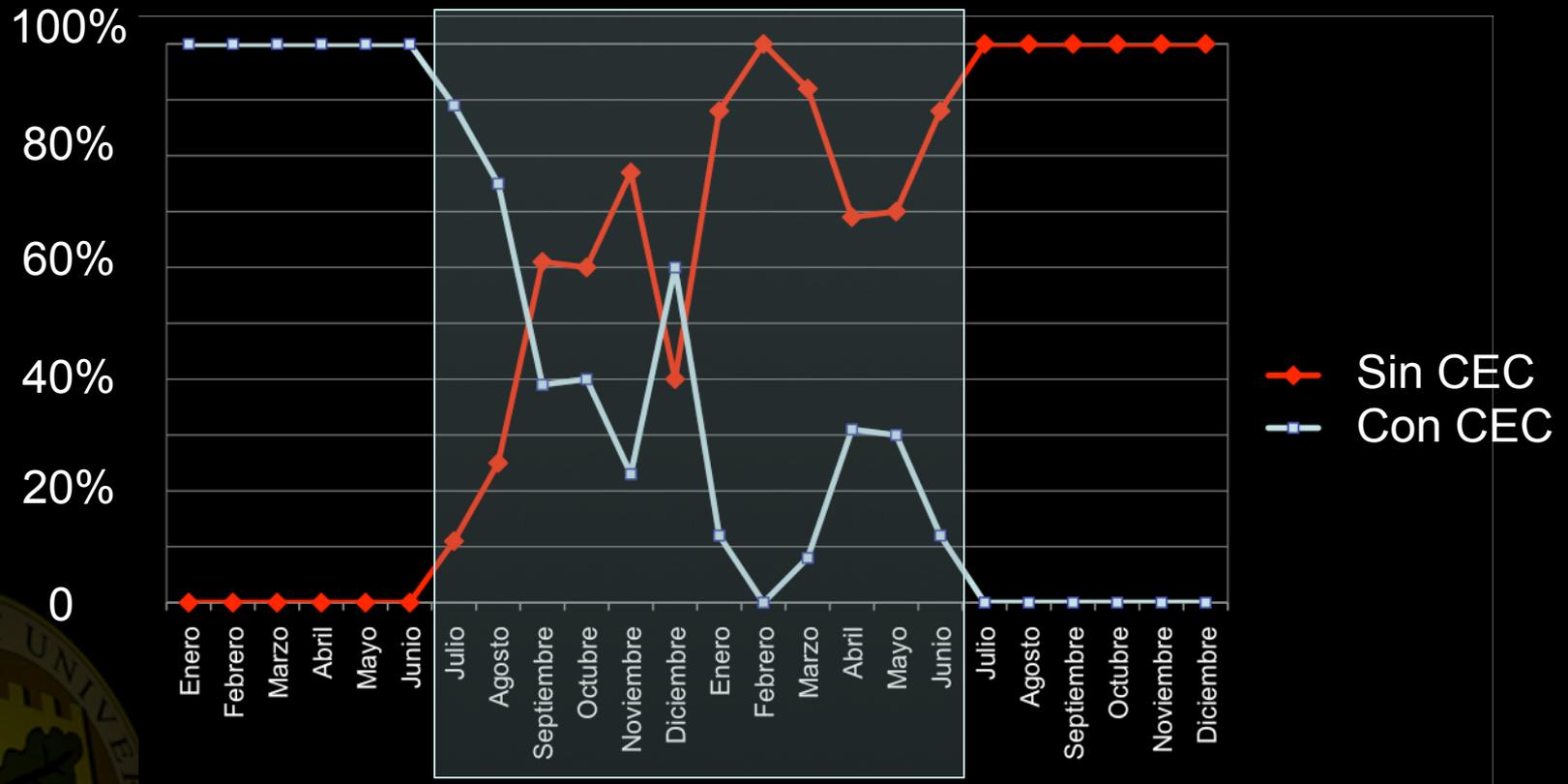
Transición hacia CRM sin CEC



Transición hacia CRM sin CEC

CRM = 138 casos – 85 Sin CEC

12 meses



2008

2009



Factores de una buena transicion

- Experto al principio
- Anestesia
- Cirujanos
- Equipamiento
- Selecccion de casos



Supervision de expertos al principio

- Cirujano de Vanderbilt me ayudo en los primeros 10 casos
- Seleccion de los casos y la conducta de la operacion
- Nota final del experto en nuestra habilidad para hacer el primer caso “solo”
- Beneficio adicional
 - Legitimidad
 - Apoyo



Factores de Anestesia

- **Antes de posicionar el corazon**
 - *PVC: 15 a 18*
 - *TA sistolica: 130 a 140*
 - *FC: 70 a 90*
- **Regulacion casi minuto a minuto con**
 - *Drogas vasoactivas*
 - *Beta bloqueantes*
 - *Marcapaso*
- **Anticipar los movimientos**
- **Inotropicos al final (*si fuera necesario*)**
- **Mantener buena temperatura**



Factores de los Cirujanos

- **Manualidad**

- Tecnicamente mas demanante

- *Vasos mas pequeños*
- *Cara lateral alta*
- *Vasos al “sur del ecuador”*
- *Intramiocardicos*
- *Es mas dificil ayudar*

- **Paciencia y Comunicacion**

- **Individualizacion de la secuencia de los puentes**

- Mamaria a descendente anterior primero.

- *Revascularizacion inmediata / poco stress*
- *Territorio miocardico extenso*

- Lesiones mas criticas

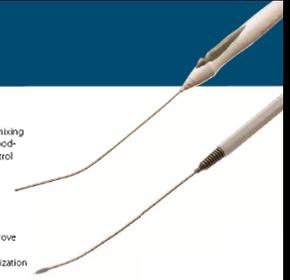


Equipamiento



AccuMist® Blower/Mister

The AccuMist® device offers advanced fluid/gas mixing technology to create a consistent, predictable blood-clearing mist. The malleable shaft and on/off control on the handpiece make it an excellent choice for facilitating a bloodless field.



ClearView® Blower/Mister

The ClearView® blower/mister is designed to improve visualization of the surgical site. An irrigation mist gently clears blood from the site, improving visualization without drying or desiccating delicate tissue.

ClearView® Intracoronary Shunt

The ClearView® shunt provides a clear anastomotic site during the procedure while providing blood flow to the distal myocardium. The soft silicone body with tapered tips is designed for atraumatic insertion and removal. Tips and tips are radiopaque. Multiple sites are available to accommodate all vessel diameters.

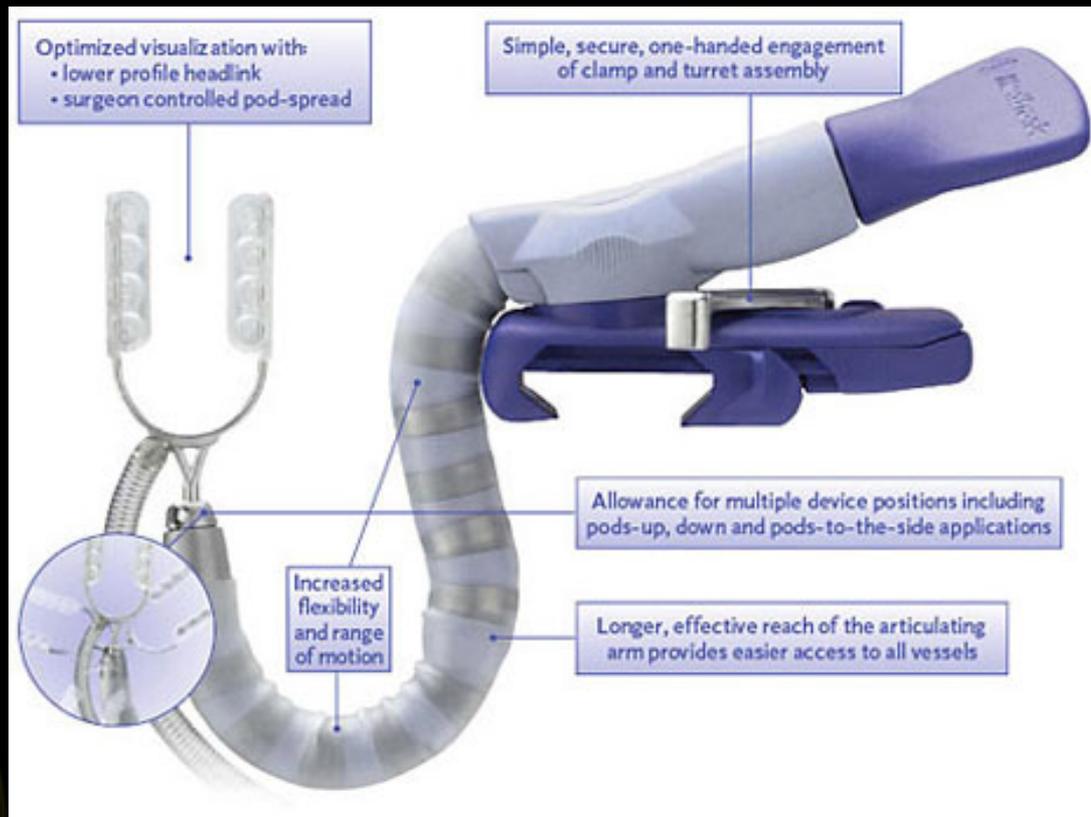


QuickFlow DPS

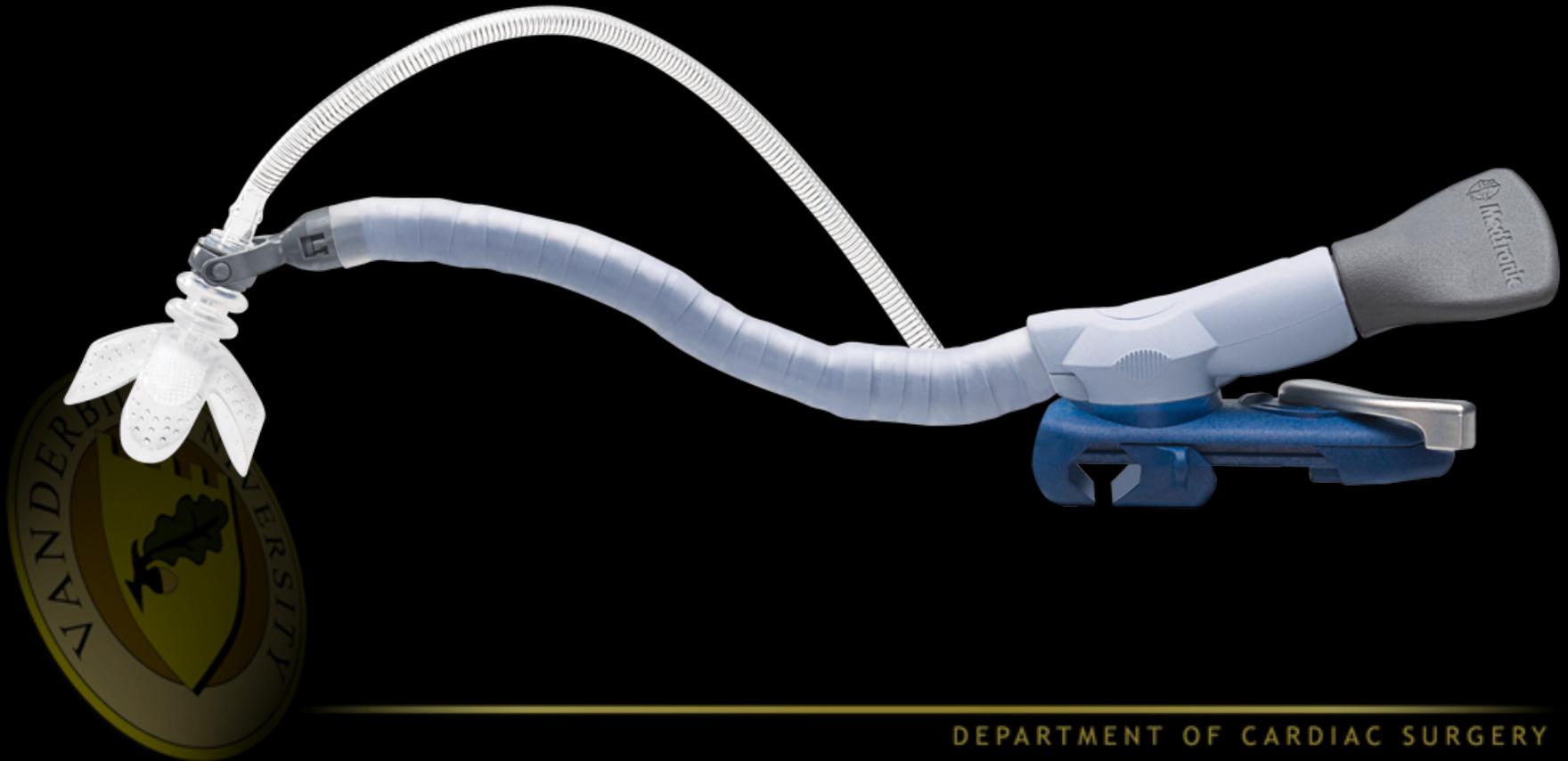
The QuickFlow DPS system contains a complete set of components designed to establish immediate aorta-to-coronary perfusion during the beating heart procedure.



Estabilizador



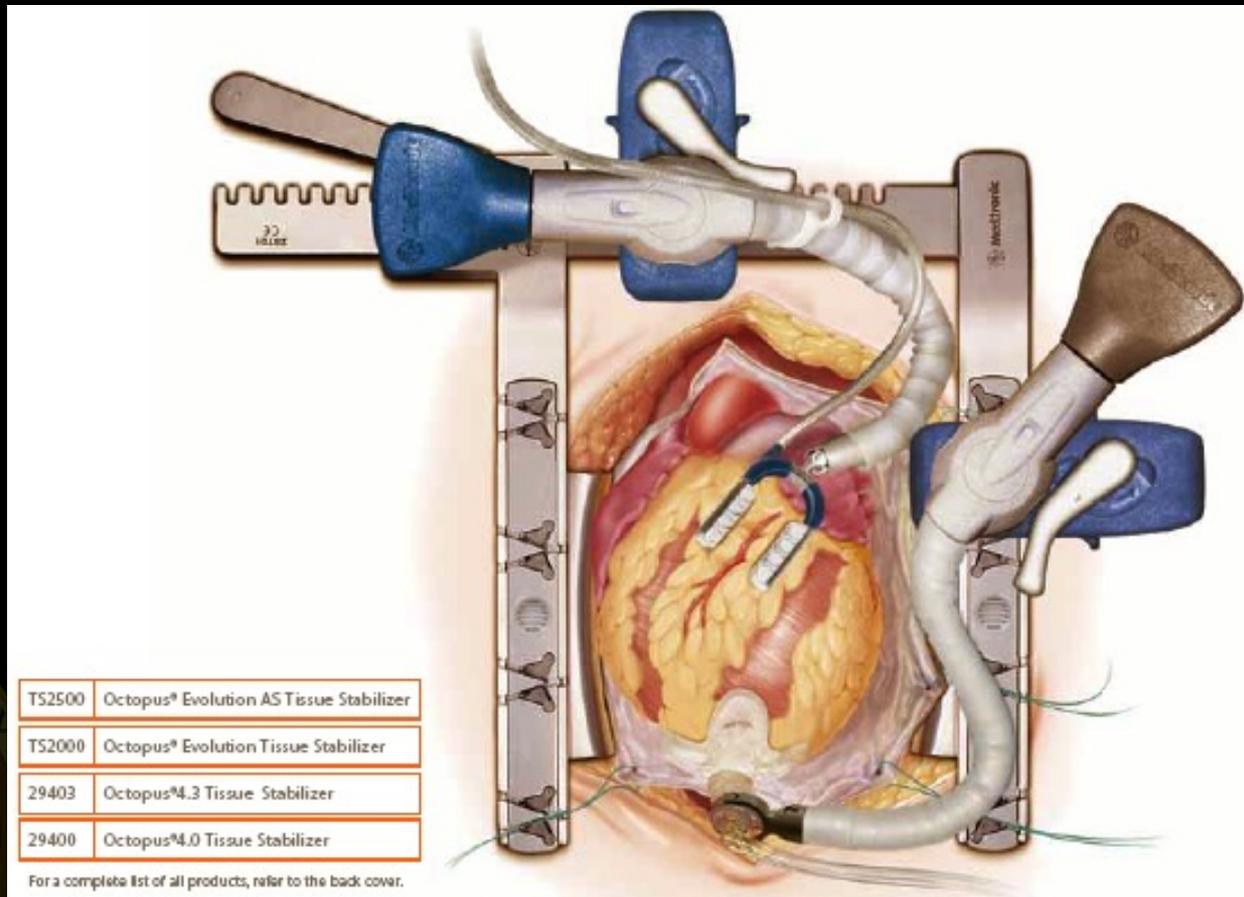
Dispositivo de Posicion



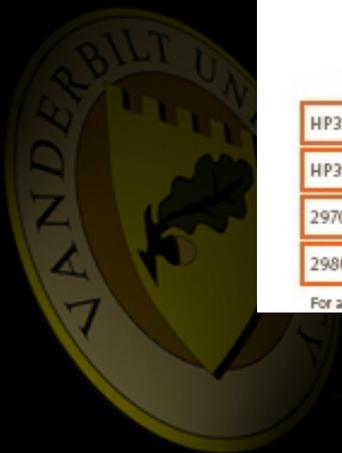
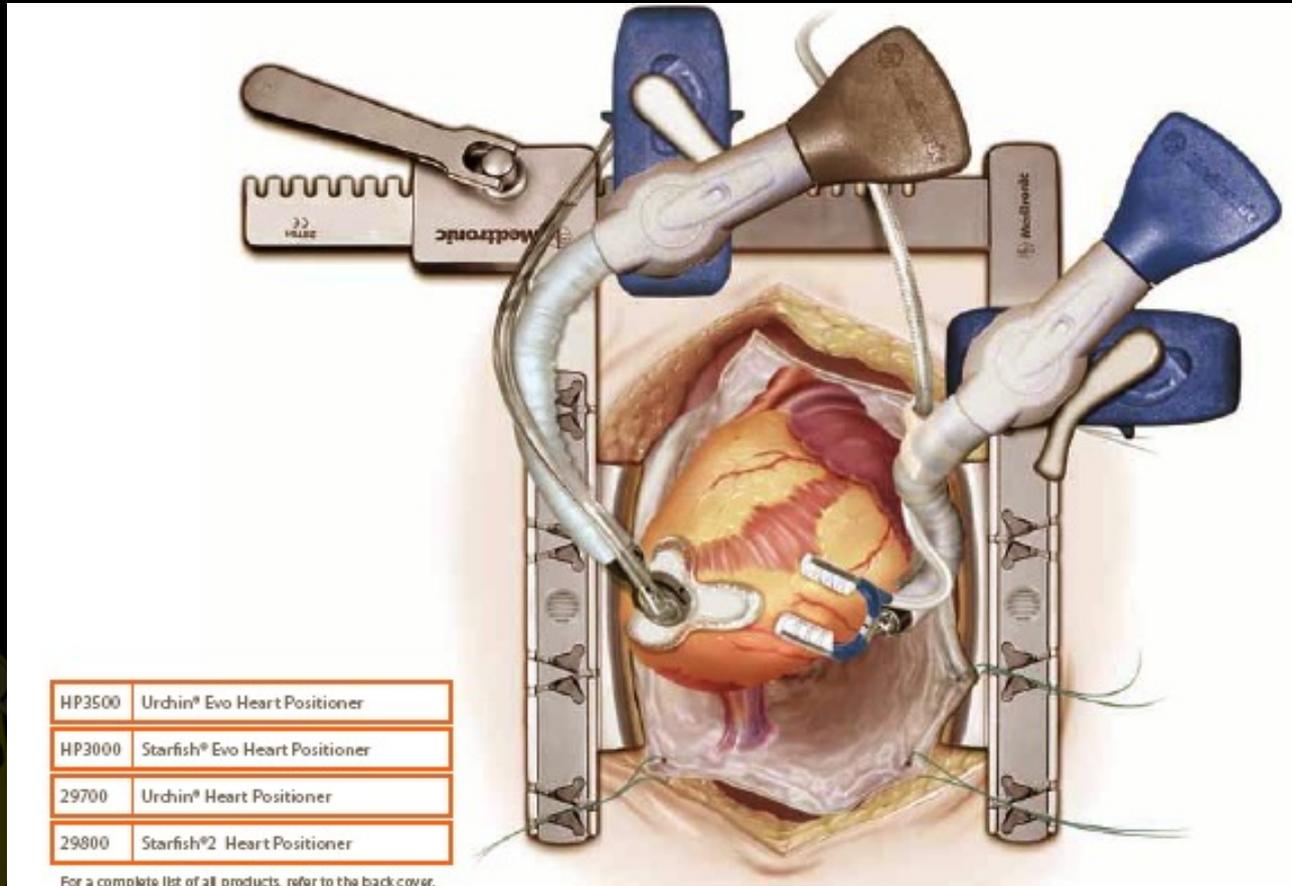
Separador



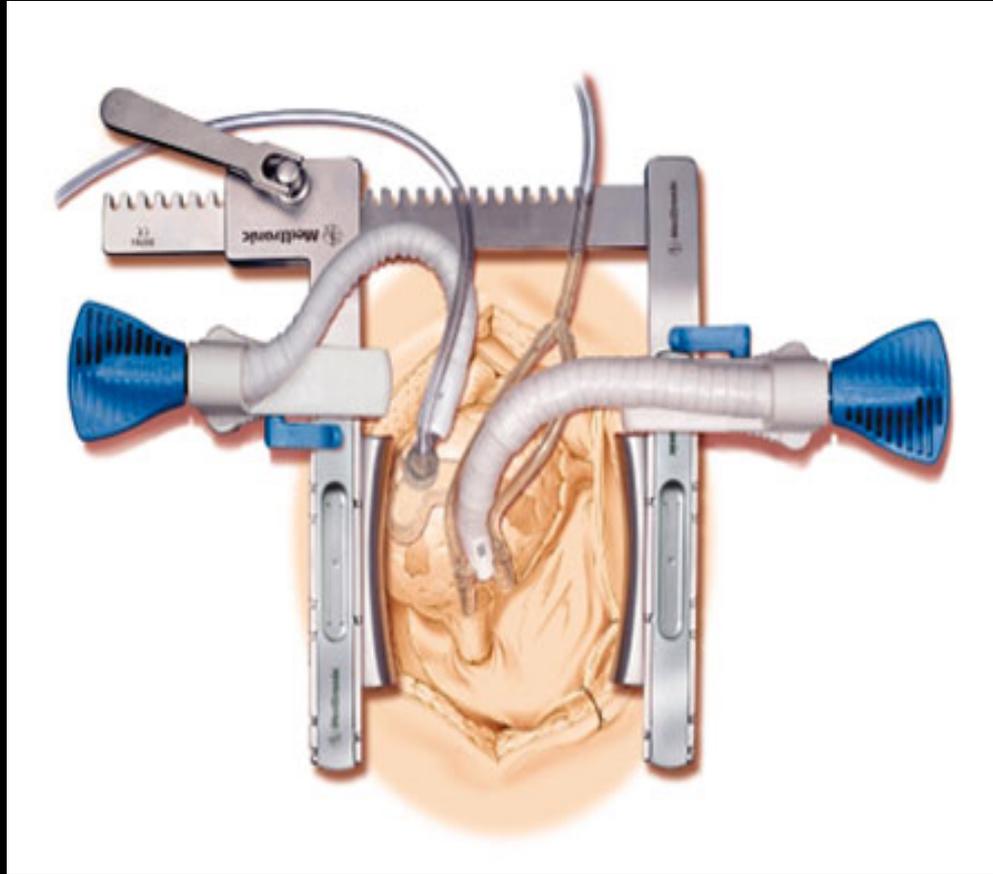
Posicion para DA



Posicion para Ramus y OM



Posicion para DP



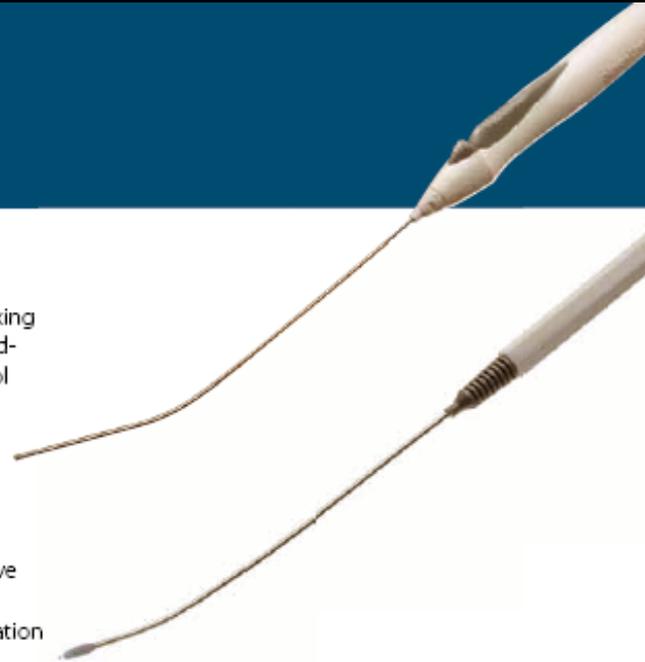
Soplador CO2

AccuMist® Blower/Mister

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ClearView® Blower/Mister

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Shunts Intracoronarios



Ventajas

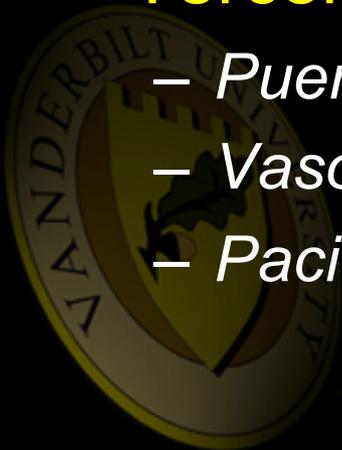
- Previene isquemia miocardica
- Disminuye el sangrado
- Minimiza errores tecnicos
- Evita el daño de las bandas de silastic alrededor de las coronarias

Desventajas

- Riesgo de diseccion del vaso
- Riesgo de perfusion prefencial
- Riesgo de atrapar el shunt con la sutura

Selección de los casos

- **Primera Etapa (caso 1- caso 10)**
 - *Mamaria a descendente anterior*
 - *Injerto venoso a la diagonal*
- **Segunda Etapa (caso 11-caso 30)**
 - *Descendiente posterior*
 - *Coronaria derecha*
- **Tercera Etapa (a partir del caso 30)**
 - *Puentes en la cara lateral*
 - *Vasos intramiocárdicos*
 - *Pacientes más inestables*



Numero de injertos y utilizacion de arteria mamaria izquierda

Etapa del programa de CRM Sin CEC

Numero de Injertos	1 - 100	101 - 230
Uno	21%	15%
Dos	55%	45%
Tres o mas	23%	39%
Promedio <i>Puentes/Paciente</i>	2.0	2.4
Utilizacion Mamaria Izq.	100 %	99 %



Numero de injertos y utilizacion de arteria mamaria izquierda

Etapa del programa de CRM Sin CEC

Numero de Injertos	1 - 100	101 - 230	
Uno	21%	15%	↓
Dos	55%	45%	
Tres o mas	23%	39%	↑
Promedio <i>Puentes/Paciente</i>	2.0	2.4	↑
Utilizacion Mamaria Izq.	100 %	99 %	



Control de Calidad (MACCE Control)

- **Mantuvimos nuestra estrategia de proteccion neurologica**
 - Ecografia aortica de superficie
 - Oximetria Cerebral
- **Redoblamos esfuerzos para asegurar la buena calidad de los puentes**
 - Cambios electricos
 - Cambios regionales en contractilidad on ETE
 - Impresion del cirujano de la calidad de la anastomosis
 - Medicion de flujo



Lecciones de nuestra curva de aprendizaje

- No es buena idea ser cirujano de CRM sin CEC ocasional
- Identificar los pacientes que no son buenos candidatos para CRM sin CEC
 - Endarterectomias
 - Vasos muy calcificados
 - Enfermedad difusa / malos lechos distales
 - Pacientes inestables (No toleran posiciones)



La Cirugia Coronaria sin Circulacion Extracorporea:

- *Por que ?*
 - *Cuales son los beneficios ?*
 - *Cuales son las desventajas ?*
 - *Que pacientes se benefician mas ?*
- *Como implementamos nuestro programa ?*
- *Que resultados obtuvimos ?*



La Cirugia Coronaria sin Circulacion Extracorporea:

- *Por que ?*
 - *Cuales son los beneficios ?*
 - *Cuales son las desventajas ?*
 - *Que pacientes se benefician mas ?*
- *Como implementamos nuestro programa ?*
- *Que resultados obtuvimos ?*



Resultados. CRM sin CEC

Nashville VA Medical Center n=200

Mortalidad	0.5%	(1/200)
Stroke	0	
TIA	0.5%	(1/200)
IAM perioperatorio	1%	(2/200)
Balon PO	1%	(2/200)
ACT < 30 dias	0	
CRM < 30 dias	0.5%	(1/200)
Conversiones a CEC	1%	(2/200)
Reop. Sangrado	1%	(2/200)
Mediastinitis	1%	(2/200)
Dialisis	1%	(2/200)



Resultados

Nashville VA Medical Center n=200

Seguimiento promedio: 11.5 meses (97% completo)

Sobrevida	97.5 %
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Sobrevida libre de IAM y revascularizacion	93.9 %
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On-Pump versus Off-Pump Coronary-Artery Bypass Surgery

A. Laurie Shroyer, Ph.D., Frederick L. Grover, M.D., Brack Hattler, M.D., Joseph F. Collins, Sc.D., Gerald O. McDonald, M.D., Elizabeth Kozora, Ph.D., John C. Lucke, M.D., Janet H. Baltz, R.N., and Dimitri Novitzky, M.D., Ph.D., for the Veterans Affairs Randomized On/Off Bypass (ROOBY) Study Group

Off-Pump vs Conventional Coronary Artery Bypass Grafting: Early and 1-Year Graft Patency, Cost, and Quality-of-Life Outcomes A Randomized Trial

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Context Previous trials of off-pump coronary artery bypass (OPCAB) have enrolled selected patients and have not rigorously evaluated long-term graft patency. A preliminary report show ed OPCAB achieved improved inhospital outcomes, similar completeness of revascularization, and shorter lengths of stay compared with conventional coronary artery bypass grafting (CABG).

Objective To assess graft patency, clinical and quality-of-life outcomes, and cost among patients while in the hospital and at 1-year follow-up.

Design, Setting, and Patients Randomized controlled trial of patients unselected for coronary anatomy, ventricular function, or comorbidities between March 10, 2000, and August 20, 2001, at a US academic center. A total of 200 patients were enrolled; 3 patients were withdrawn after randomization for mitral valve repair or replacement. Follow-up was complete for 197 patients at 30 days; 185 at 1 year.

Interventions One surgical session consisting of elective OPCAB or CABG with cardiopulmonary bypass. The surgeon had extensive experience performing off-pump surgery; patients were subsequently managed by blinded protocols.

Main Outcome Measures Coronary angiography documented graft patency prior to hospital discharge and at 1 year; health-related quality of life; and cost of the index and subsequent hospitalization(s).

Results CABG patency was similar for OPCAB and conventional CABG with cardiac

ROOBY Study. NEJM 2009

Puskas et al
JAMA 2004

Resultados: Nashville VA

	Nashville VA Medical Center	ROOBY Sin CEC	Puskas Sin CEC
Mortalidad	0.5%	1.6%	1 %
Stroke	0	1.3%	1 %
Coma	0	0.4%	
Balon PO	1%	1.5%	
Cardiac Arrest	1%	1.8%	1 %
Reop. Sangrado	1%	2.7%	1 %
Dialisis (PO)	1%	0.8%	2 %

ROOBY Study. NEJM 2009 Puskas et al. JAMA 2004

Resultados: Comparados con ROOBY y PUKAS

Nashville VA
Medical Center

ROOBY
Sin CEC

Puskas
Sin CEC

Mortalidad (1 año)
Cualquier Causa

2.5 %

4.1 %

4.4 %

Mortalidad (1 año)
Causas Cardiacas

1.5 %

2.7 %

Revascularizacion
> 30 dias < 1 año

3.6 %

4.6 %

2.2 %

IAM no fatal
>30 dias < 1 año

0

2.0 %

1 %

ROOBY Study. NEJM 2009

DEPARTMENT OF CARDIAC SURGERY

Resultados comparados con ROOBY

Nashville VA Medical Center ROOBY Study
Sin CEC Con CEC

Mortalidad (1 año) Cualquier Causa	2.5 %	4.1 %	2.9 %
Mortalidad (1 año) Causas Cardiacas	1.5 %	2.7 %	1.3 % *
Revascularizacion > 30 dias < 1 año	3.6 %	4.6 %	3.4 %
IAM no fatal >30 dias < 1 año	0	2.0 %	2.2 %

ROOBY Study. NEJM 2009

DEPARTMENT OF CARDIAC SURGERY

Resultados: ROOBY: CRM con y sin CEC

Nashville VA Medical Center (CRM sin CEC)

Nashville VA
Medical Center

ROOBY Study
Sin CEC Con CEC

Todos los end points (1 año)
Mortalidad Cualquier Causa

6.1 %

9.9 %

7.4 % *

Todos los endpoints (1 año)
Mortalidad Cardiaca

5.1 %

8.8 %

5.9 % *

Todos los end points < año
+ complicaciones < 30 dias

9.6 %

14.6 %

9.9 % *

ROOBY Study. NEJM 2009



Conclusion

- Se pueden obtener buenos resultados en la transición hacia CRM sin CEC
- Es conveniente abordar cada paciente coronario como candidato a CRM sin CEC
- La CRM sin CEC requiere un mayor esfuerzo, colaboración y comunicación por parte de Cirujanos y Anestesiistas
- La selección de los casos y el rol del experto son muy importantes, sobre todo al principio

Muchas Gracias

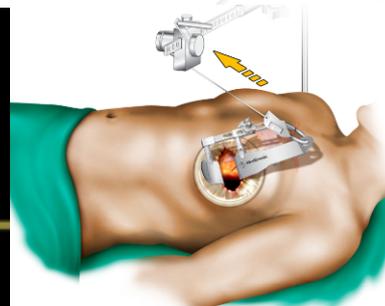
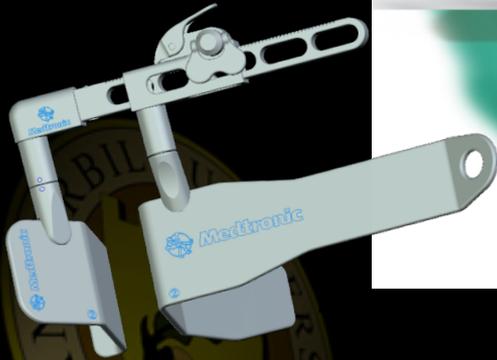
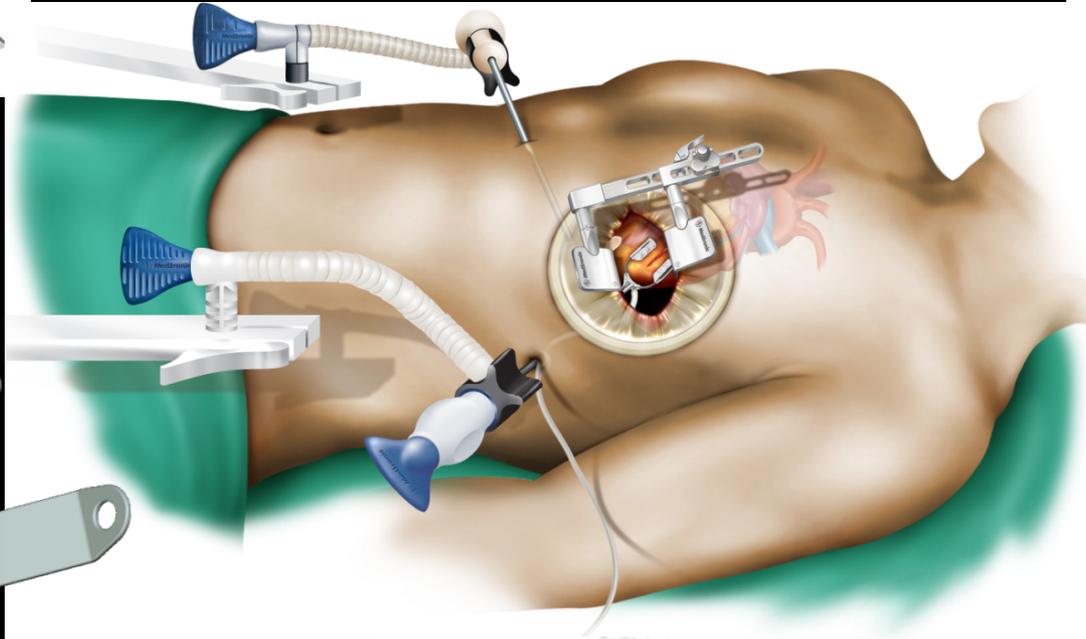




DEPARTMENT OF CARDIAC SURGERY

MICS CABG

Putting the future of MICS in your hands today

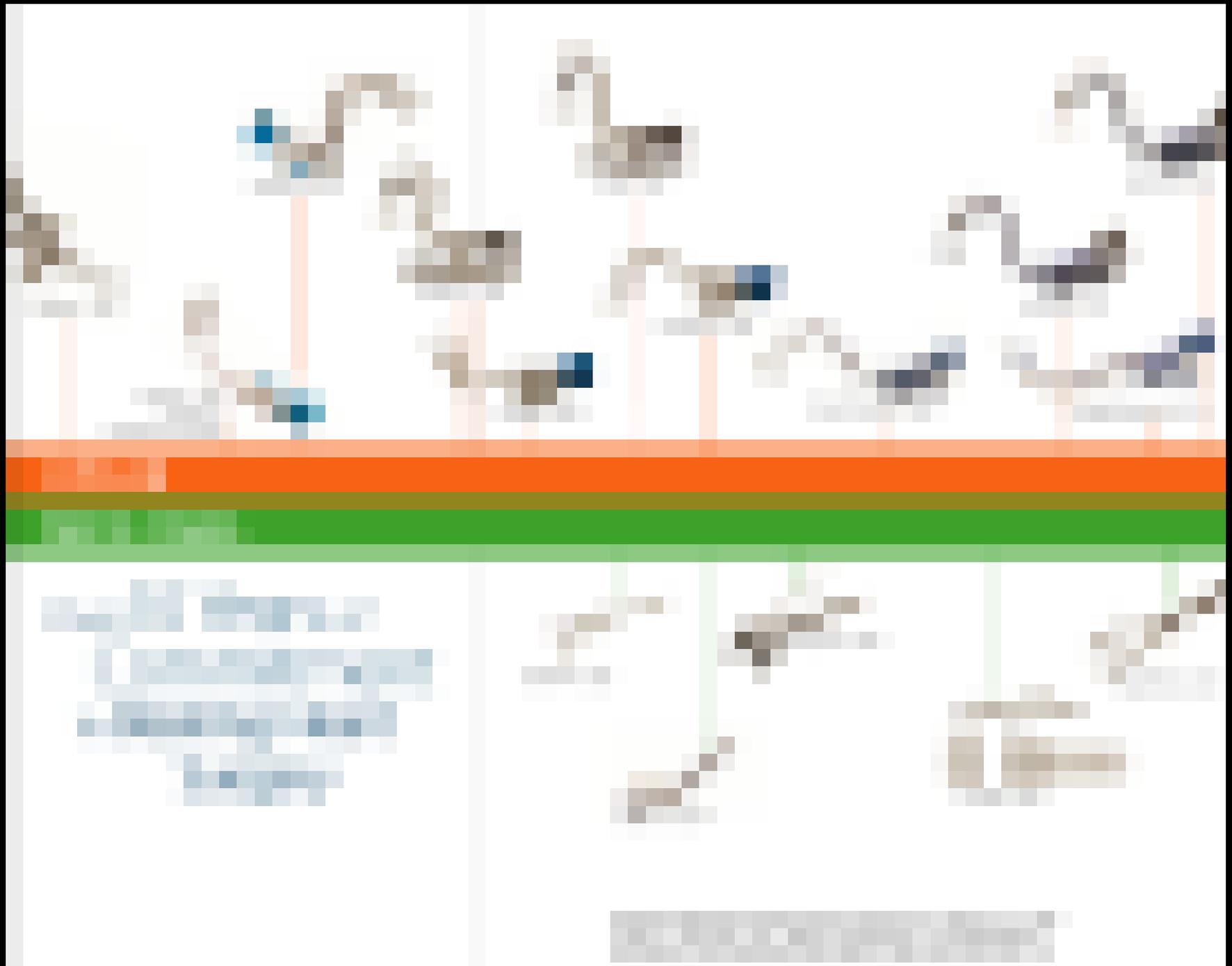


ISMICS Consensus Statement

Puskas, et. al. (continued)

- OPCAB should be considered in high-risk patients and those with risk factors to reduce peri-operative mortality, morbidity, and resource allocation.
 - Patients over 75
 - Diabetics
 - Left ventricular function
 - Left Main Disease
 - Redo or Urgent/Emergent CABG
 - COPD





Estabilizador



Estabilizador

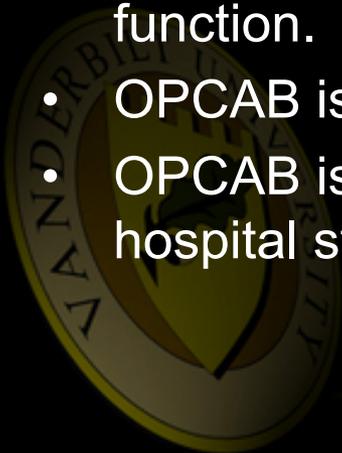


ISMICS Consensus Statement

Puskas, et. al.

Recommendations:

- OPCAB is a safe alternative to conventional CABG with respect to mortality.
- With appropriate use of stabilizers and positioners, and adequate surgeon experience, completeness of revascularization and patency can be achieved.
- OPCAB is recommended to reduce peri-op. mortality.
- OPCAB may be recommended to reduce mid-term cognitive function.
- OPCAB is equiv. for Quality of Life.
- OPCAB is recommended to reduce duration of ventilation, ICU and hospital stays, and resource utilization.



Meta-analysis: Cheng (continued)

- When compared to CCABG, OPCAB reduced the odds of:
 - AF by 42%
 - Transfusions by 57%
 - Need for Inotropes by 52%
 - Respiratory infections by 59%
 - Neurocog. Dysfunctions at 2-6 mos. By 44%
 - Vent. Time by 3.4 hours
 - Average ICU stay by 0.3 days
 - Average hospital length of stay by 1.0 days.



Matched Sample Analysis: Mack

On-Pump Versus Off-Pump Coronary Artery Bypass Surgery in a Matched Sample of Women A Comparison of Outcomes

Michael J. Mack, MD; Phillip Brown, MD; Frank Houser, MD; Mark Katz, MD;
Aaron Kugelmass, MD; April Simon, MSN; Salvatore Battaglia, BS; Lynn Tarkington, RN;
Steven Culler, PhD; Edmund Becker, PhD

Background—Women have consistently higher mortality and morbidity than men after coronary artery bypass grafting (CABG). Whether elimination of cardiopulmonary bypass and performance of coronary artery bypass grafting off-pump (OPCAB) have a beneficial effect specifically in women has not been defined.

Methods and Results—From January 1998 through March 2002, 21 902 consecutive female patients at 82 hospitals underwent isolated CABG, as reported in an administrative database. Propensity score computer matching was performed based on 13 variables representing patient characteristics and preoperative risk factors to correct for and minimize selection bias. A total of 7376 (3688 pairs) women undergoing CABG surgery were able to be successfully matched. In a propensity score computer-matched cohort, multivariate logistic regression (odds ratio) revealed that women undergoing on-pump surgery had a 73.3% higher mortality ($P=0.002$) and a 47.2% higher risk of bleeding complications ($P=0.019$).

Conclusions—In a retrospective analysis of women undergoing CABG, computer-matched to minimize selection bias, off-pump surgery led to decreased mortality and morbidity including bleeding complications. (*Circulation*. 2004; 110[suppl II]:II-1-II-6.)

Key Words: mortality ■ sex ■ cardiopulmonary bypass ■ women ■ surgery ■ administrative data

Coronary artery disease is the leading cause of mortality in women, with 250 000 deaths annually, easily surpassing breast cancer as the leading cause.¹ Furthermore, more women than men die each year of heart disease.² Numerous studies have shown that women have a 1.5- to 2-times higher mortality rate after coronary artery bypass grafting (CABG) than men.³⁻¹² Possible reasons for this increased mortality include a higher preoperative risk profile, including later clinical presentation,⁸ more acute presentation,⁵ older age,⁹ higher incidence of diabetes mellitus,⁷ higher incidence of left ventricular hypertrophy and hypertensive heart disease,^{1,13} and smaller coronary arteries.^{14,15}

Off-pump CABG (OPCAB) has been introduced as a technique to lessen overall operative mortality and morbidity. Numerous series indicate that there may be some overall benefit to off-pump surgery,¹⁶⁻¹⁸ as well as a select benefit in certain high-risk subgroups.^{19,20} Two retrospective analyses have shown a decreased, but not statistically significant, mortality in women undergoing CABG off-pump compared with on-pump CABG.^{21,22} Because no randomized trial of OPCAB versus on-pump CABG in women exists, we retrospectively reviewed CABG outcomes in women in a

large hospital system database. To minimize the effect of selection bias on outcomes, we used the technique of propensity score computer-matching of preoperative risk factors to obtain a valid comparison between the 2 treatment groups.²³⁻²⁷

Methods

Study Population

All patients undergoing isolated CABG in the HCA, Inc hospital system are captured in the HCA Casemix Database. The HCA Casemix Database is a comprehensive administrative database containing patient, clinical, and outcome data on all cardiovascular patients at all HCA hospitals. Data are coded by *International Classification in Diseases*, 9th edition, Clinical Modification (ICD-9CM) codes from UB-92 billing information. There are 15 diagnostic codes (1 primary and 14 secondary codes) and 9 procedural codes (1 primary and 8 secondary) in the database. Data in this study were captured over a 17-quarter study period (51 months) from January 1, 1998 through March 31, 2002. All consecutive female patients undergoing isolated CABG in a total of 82 mainly community-based hospitals were included.

A propensity score computer-matched sample was used to create equivalent treatment groups. Initially, a total of 21 902 consecutive women patients at the 82 hospitals and discharged into 1 of the 3

From HCA, Inc (M.J.M., P.B., F.H., M.K., A.K., S.B., L.T.), Nashville, Tenn; Cardiac Data Solutions, Inc (A.S.), Zionsville, Ind; and Rollins School of Public Health at Emory University (S.C., E.B.), Atlanta, Ga.
Presented at American Heart Association Scientific Sessions, November 9-12, 2003, Orlando, Florida.
Correspondence to Michael J. Mack, MD, 7777 Forest Lane, Suite A333, Dallas, TX 75230. E-mail smullins@csant.com
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Circulation is available at <http://www.circulationaha.org>

DOI: 10.1161/01.CIR.0000138198.62961.41

Retrospective analysis 21,902 female patients undergoing bypass on or off.

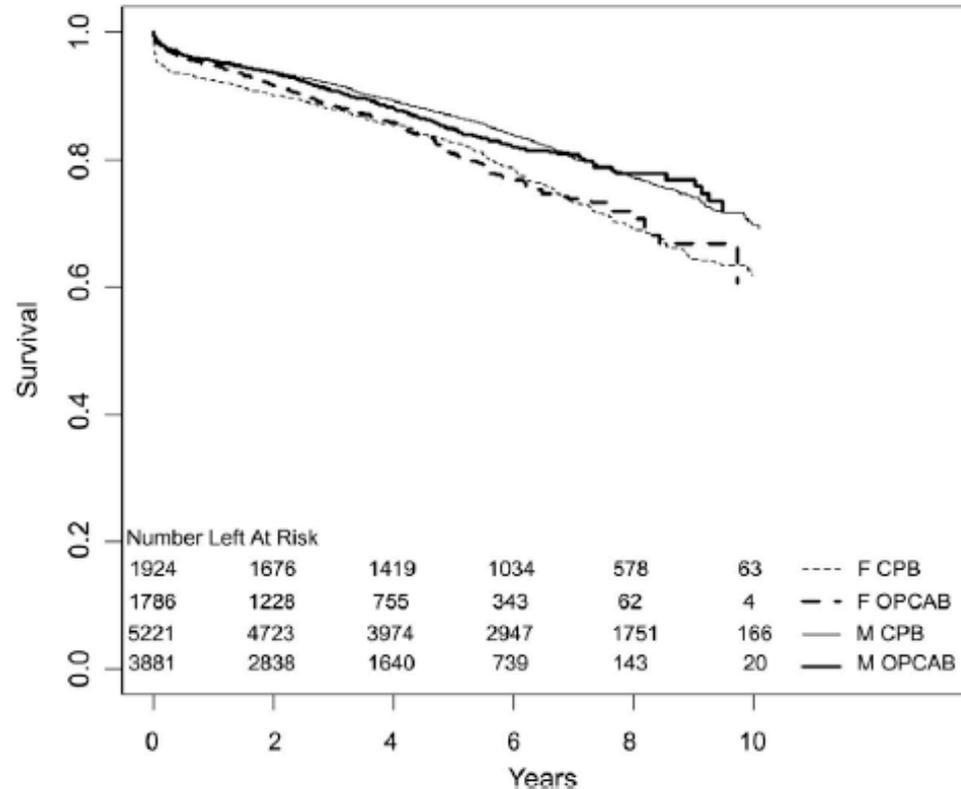
Women undergoing on-pump surgery had:

- 73.3% higher mortality
- 47% higher risk of bleeding complications

As stated by the authors: “Our data support a specific and significant benefit to off-pump surgery in women.”

Sobrevivida Alejada

Fig 2. Kaplan-Meier 10-year survival curve by gender and coronary artery bypass (CAB) grafting procedures with cardiopulmonary bypass (CPB) or off-pump (OPCAB). (F = females—small dashed line, CPB; large dashed line, OPCAB. M = males—thin line, CPB; thick line, OPCAB.)



Puskasy col. Ann Thorac Surg 2008

Numero de injertos y utilizacion de arteria mamaria izquierda

Etapa del programa de CRM Sin CEC

Numero de Injertos	1-50	51-100	101-150	151-200	200-230
Uno	9	12	10	8	4
Dos	26	29	28	18	17
Tres	14	9	11	22	15
Cuatro	0	0	1	2	4
Promedio <i>Puentes/Paciente</i>	2.1	1.8	2.1	2.4	2.4
<i>Utilizacion</i> <i>Mamaria Izq.</i>	100 %	100 %	98 %	98 %	100 %

140 injertos en la cara lateral

Nuestra poblacion de pacientes coronarios es de alto riesgo

	Syntax	ROOBY	Puskas	NashvilleVA
Diabetes	25%	42%	32%	49%
HTN	64%	86%	61%	98%
EPOC		20%	10%	21%
Tabaquismo (Actual)	22%	32%	27%	41%
Enf. Vasc Perisferica		16%	13%	36%
Enf. Cerebrovascular				26%
Stroke previo	5%	7%	1%	12%



Comparacion de Poblaciones

	Syntax	ROOBY	Puskas	NashvilleVA
IAM previo	33%		34%	45%
Angina (III-IV)			24%	51%
Angina Inestable	20%	10%	21%	44%
IABP previo				6.5%
ATC previa	0		32%	32%
CRM previa	0	1%		1%
Operacion				
No electiva	5%	7%	16%	31%
FE VI =< 35%		6%	9%	13%
<u>Anatomia Coronaria</u>				
Un vaso	6%			
Dos Vasos	29%			
Tres vasos	65%			
Tronco de la CI				

Resultados: Nashville VA

	Nashville VA Medical Center	ROOBY Study Sin CEC	ROOBY Study Con CEC
Mortalidad	0.5%	1.6%	1.2%
Stroke	0	1.3%	0.7%
Coma	0	0.4%	0.3%
Balon PO	1%	1.5%	0.8%
Cardiac Arrest	1%	1.8%	1%
Reop. Sangrado	1%	2.7%	2.1%
Dialisis (PO)	1%	0.8%	0.9%

ROOBY Study. NEJM 2009



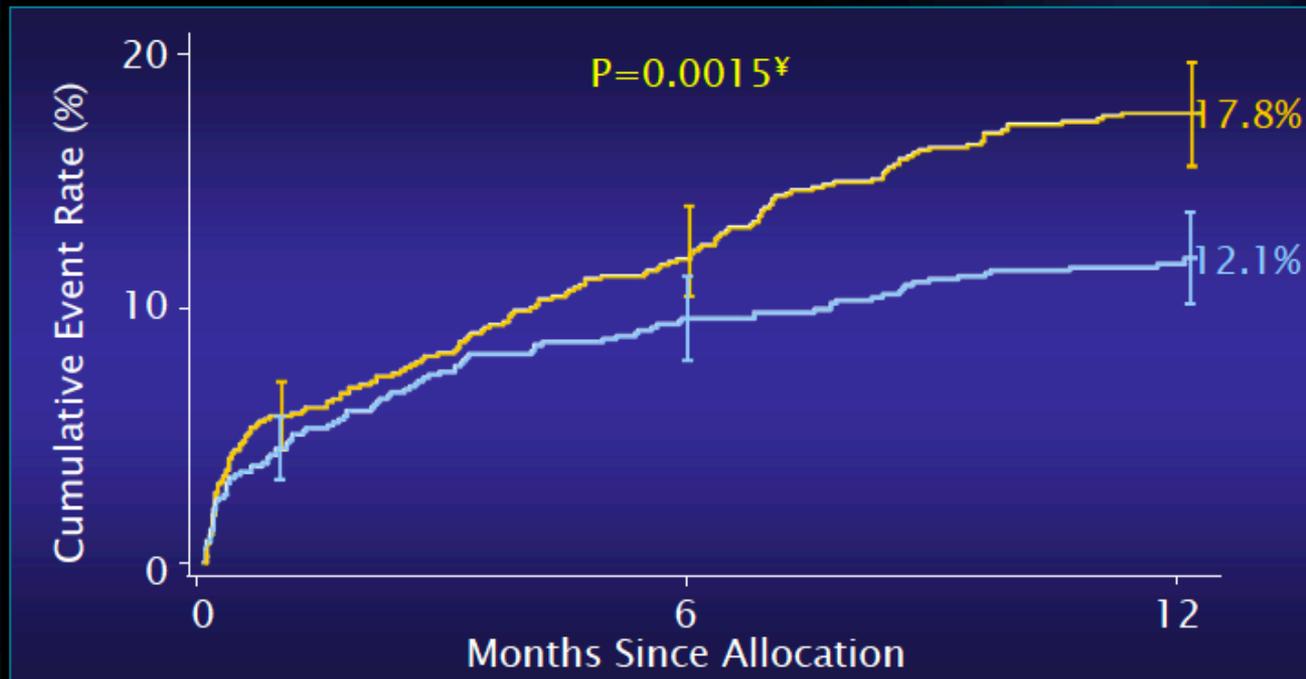
Comparados con CRM en el estudio Syntax

MACCE to 12 Months: Primary Endpoint

SYNTAX

■ CABG (N=897)

■ TAXUS* (N=903)



Event Rate \pm 1.5 SE ITT population
*Fisher Exact Test

*TAXUS® Express® Stent System

ES 2009

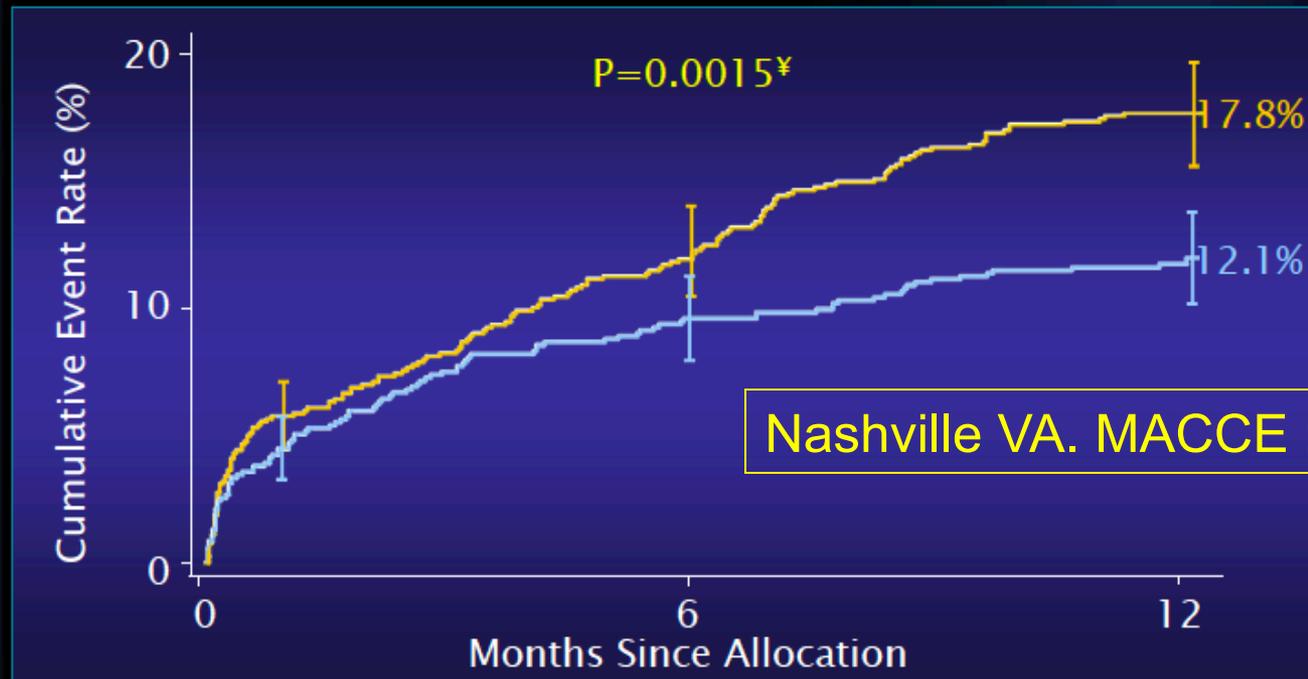
Comparado a CRM en Syntax

MACCE to 12 Months: Primary Endpoint

SYNTAX

■ CABG (N=897)

■ TAXUS* (N=903)



Event Rate \pm 1.5 SE ITT population
*Fisher Exact Test

*TAXUS® Express® Stent System

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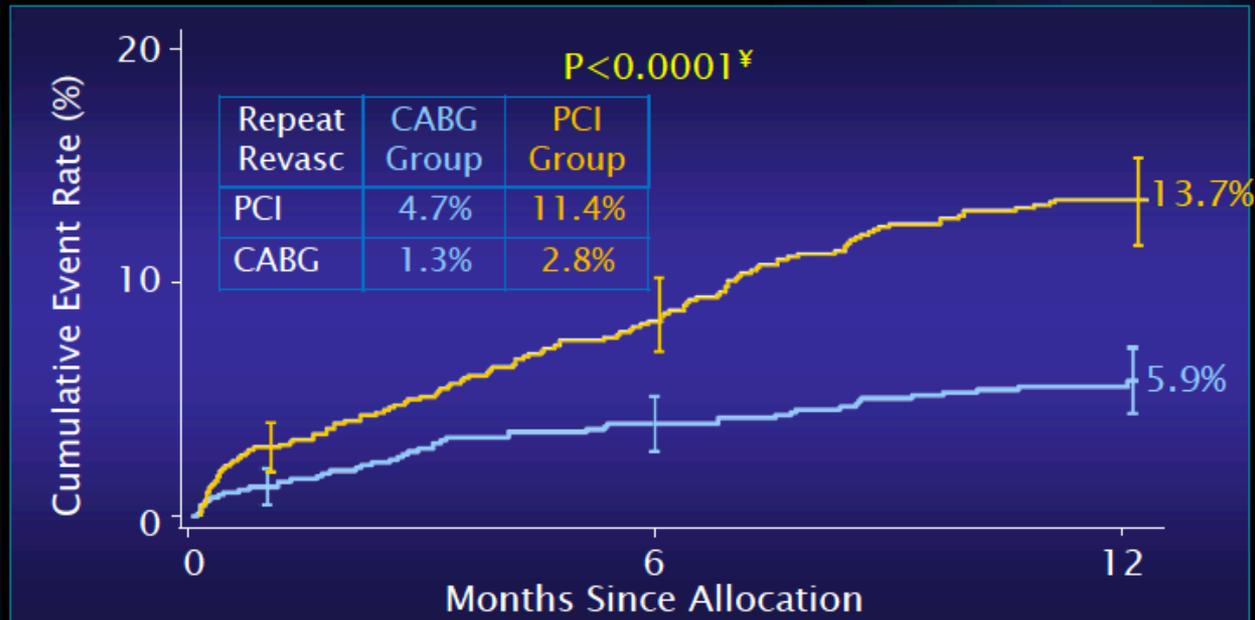
Comparado a CRM en Syntax

Repeat Revascularization to 12 Months

SYNTAX)

■ CABG (N=897)

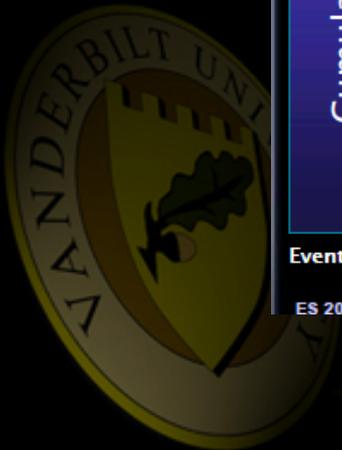
■ TAXUS* (N=903)



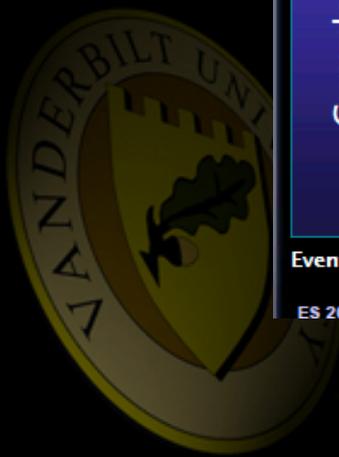
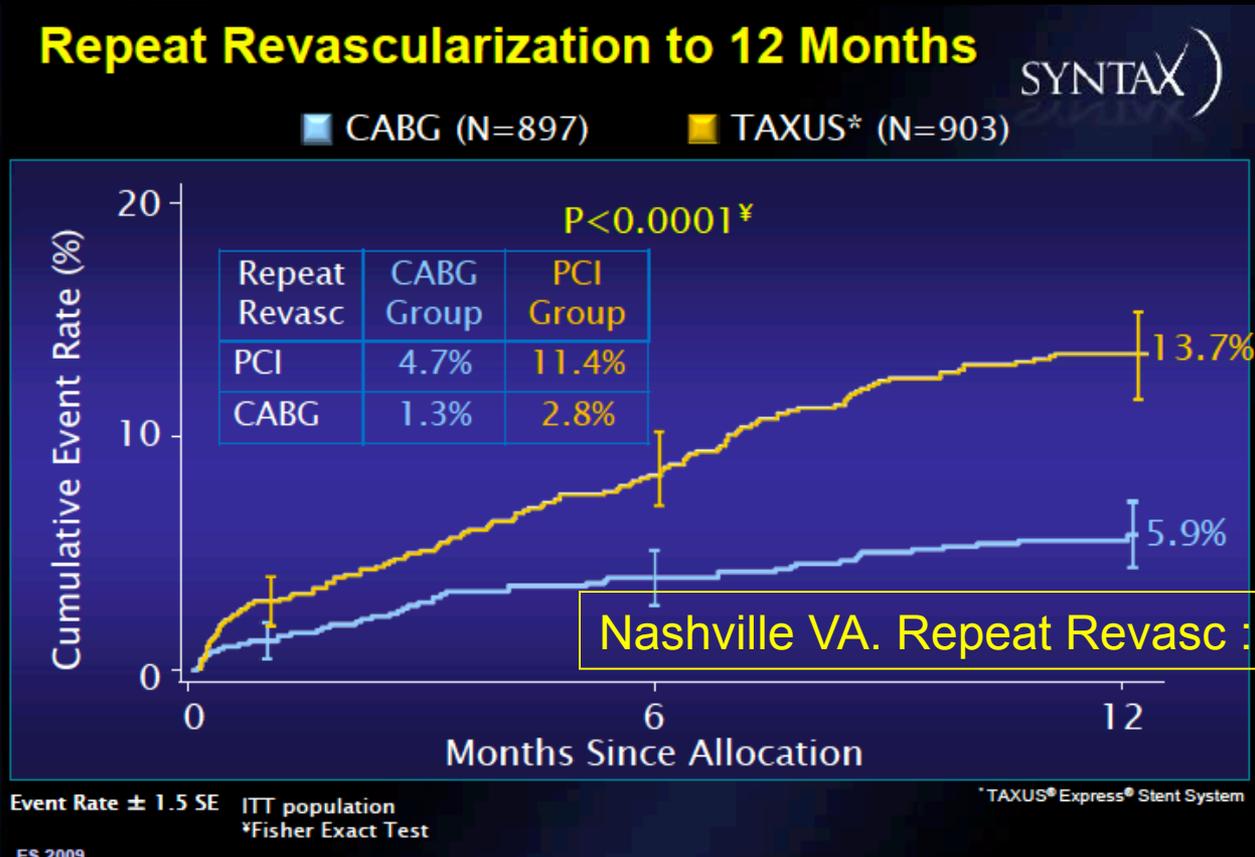
Event Rate \pm 1.5 SE ITT population
*Fisher Exact Test

*TAXUS® Express® Stent System

ES 2009



Comparado a CRM en Syntax



Nuestra poblacion de pacientes coronarios es de alto riesgo

	Syntax	Nashville VA
Diabetes	25%	46%
Unstable Angina	28%	44%
FE < 30%	1.5%	7%
CVD	8%	16%
TIA	4%	6%
* Stroke previo	5%	12%
Euroscore (Promedio)	3.8	8
Euroscore > 6	20%	31%
Urgente	4%	48%
Balon preoperatorio		14%

* Nuestra Circulacion Extracorporea esta por debajo del nivel de excelencia

