



Programa “PRINCE”

Angioplastía Transluminal Coronaria Primaria en Puerto Rico

7ma Convención Annual de
Cardiología Intervencional/
XXIII JORNADAS SOLACI

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San Juan, Puerto Rico



Classification of Recommendations and Levels of Evidence

	CLASS I <i>Benefit >>> Risk</i> Procedure/Treatment SHOULD be performed/administered	CLASS IIa <i>Benefit >> Risk</i> Additional studies with focused objectives needed IT IS REASONABLE to perform procedure/administer treatment	CLASS IIb <i>Benefit ≥ Risk</i> Additional studies with broad objectives needed; additional registry data would be helpful Procedure/Treatment MAY BE CONSIDERED	CLASS III <i>No Benefit or CLASS III Harm</i> <table border="1"> <thead> <tr> <th></th> <th>Procedure/ Test</th> <th>Treatment</th> </tr> </thead> <tbody> <tr> <td>COR III: No Benefit</td> <td>Not Helpful</td> <td>Has Proven Benefit</td> </tr> <tr> <td>COR III: Harm</td> <td>Excess Cost w/o Benefit or Harmful</td> <td>Harmful to Patients</td> </tr> </tbody> </table>		Procedure/ Test	Treatment	COR III: No Benefit	Not Helpful	Has Proven Benefit	COR III: Harm	Excess Cost w/o Benefit or Harmful	Harmful to Patients
	Procedure/ Test	Treatment											
COR III: No Benefit	Not Helpful	Has Proven Benefit											
COR III: Harm	Excess Cost w/o Benefit or Harmful	Harmful to Patients											
LEVEL A Multiple populations evaluated* Data derived from multiple randomized clinical trials or meta-analyses	<ul style="list-style-type: none"> Recommendation that procedure or treatment is useful/effective Sufficient evidence from multiple randomized trials or meta-analyses 	<ul style="list-style-type: none"> Recommendation in favor of treatment or procedure being useful/effective Some conflicting evidence from multiple randomized trials or meta-analyses 	<ul style="list-style-type: none"> Recommendation's usefulness/efficacy less well established Greater conflicting evidence from multiple randomized trials or meta-analyses 	<ul style="list-style-type: none"> Recommendation that procedure or treatment is not useful/effective and may be harmful Sufficient evidence from multiple randomized trials or meta-analyses 									
LEVEL B Limited populations evaluated* Data derived from a single randomized trial or nonrandomized studies	<ul style="list-style-type: none"> Recommendation that procedure or treatment is useful/effective Evidence from single randomized trial or nonrandomized studies 	<ul style="list-style-type: none"> Recommendation in favor of treatment or procedure being useful/effective Some conflicting evidence from single randomized trial or nonrandomized studies 	<ul style="list-style-type: none"> Recommendation's usefulness/efficacy less well established Greater conflicting evidence from single randomized trial or nonrandomized studies 	<ul style="list-style-type: none"> Recommendation that procedure or treatment is not useful/effective and may be harmful Evidence from single randomized trial or nonrandomized studies 									
LEVEL C Very limited populations evaluated* Only consensus opinion of experts, case studies, or standard of care	<ul style="list-style-type: none"> Recommendation that procedure or treatment is useful/effective Only expert opinion, case studies, or standard of care 	<ul style="list-style-type: none"> Recommendation in favor of treatment or procedure being useful/effective Only diverging expert opinion, case studies, or standard of care 	<ul style="list-style-type: none"> Recommendation's usefulness/efficacy less well established Only diverging expert opinion, case studies, or standard of care 	<ul style="list-style-type: none"> Recommendation that procedure or treatment is not useful/effective and may be harmful Only expert opinion, case studies, or standard of care 									
Suggested phrases for writing recommendations	should is recommended is indicated is useful/effective/beneficial	is reasonable can be useful/effective/beneficial is probably recommended or indicated	may/might be considered may/might be reasonable usefulness/effectiveness is unknown/unclear/uncertain or not well established	COR II: No Benefit is not recommended is not indicated	COR II: Harm potentially harmful causes harm associated with excess morbidity/mortality								
Comparative effectiveness phrases*	treatment/strategy A is recommended/indicated in preference to treatment B treatment A should be chosen over treatment B	treatment/strategy A is probably recommended/indicated in preference to treatment B it is reasonable to choose treatment A over treatment B		should not be performed/administered/other is not useful/beneficial/effective	should not be performed/administered/other								

A recommendation with Level of Evidence B or C does not imply that the recommendation is weak. Many important clinical questions addressed in the guidelines do not lend themselves to clinical trials. Although randomized trials are unavailable, there may be a very clear clinical consensus that a particular test or therapy is useful or effective.

*Data available from clinical trials or registries about the usefulness/efficacy in different subpopulations, such as sex, age, history of diabetes, history of prior myocardial infarction, history of heart failure, and prior aspirin use.

†For comparative effectiveness recommendations (Class I and IIa; Level of Evidence A and B only), studies that support the use of comparator verbs should involve direct comparisons of the treatments or strategies being evaluated.

Onset of Myocardial Infarction

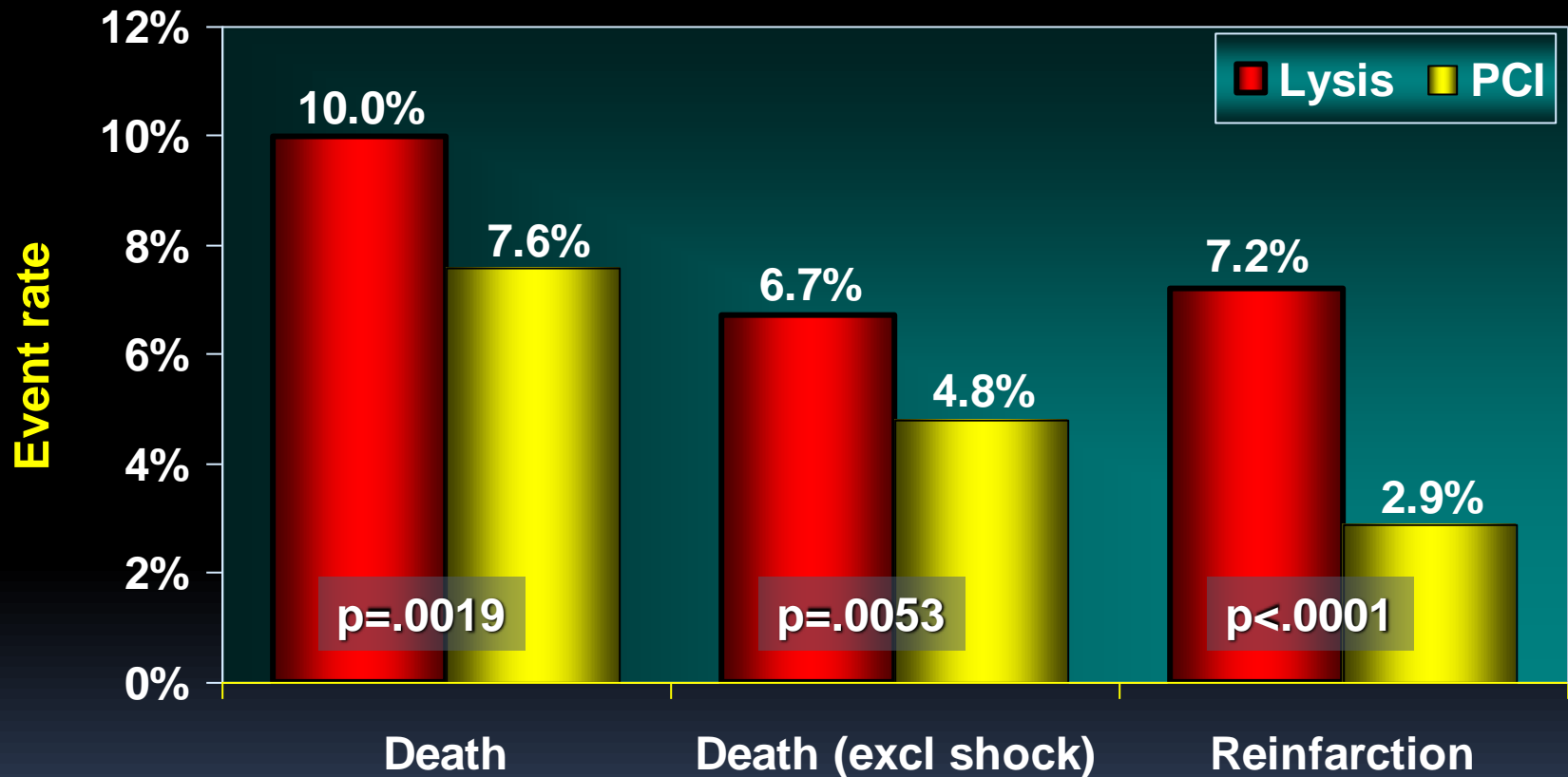
Community Preparedness and
System Goals for Reperfusion
Therapy

Onset of Myocardial Infarction

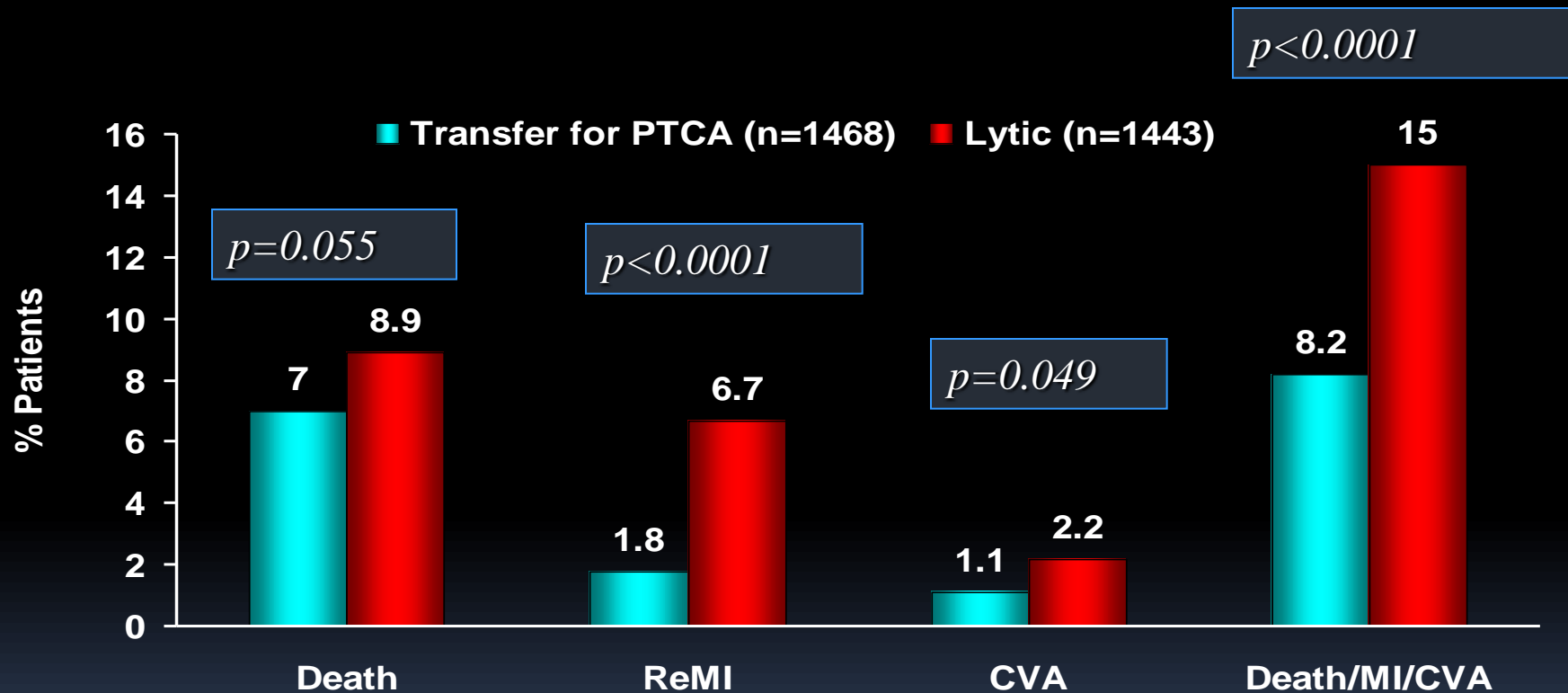
Regional Systems of STEMI
Care, Reperfusion Therapy, and
Time-to-Treatment Goals

19 Randomized Trials of PCI vs. Lysis

N = 5,066



Transfer for Primary PTCA vs On-Site Lytics (Pooled Data from 5 Randomized Trials*)



*LIMI, Prague I & II, Air PAMI, DANAMI-II trials

Keeley & Grines, *Lancet* 2003;361:13-20

Regional Systems of STEMI Care, Reperfusion Therapy, and Time-to-Treatment Goals



Reperfusion therapy should be administered to all eligible patients with STEMI with symptom onset within the prior 12 hours.



Primary PCI is the recommended method of reperfusion when it can be performed in a timely fashion by experienced operators.



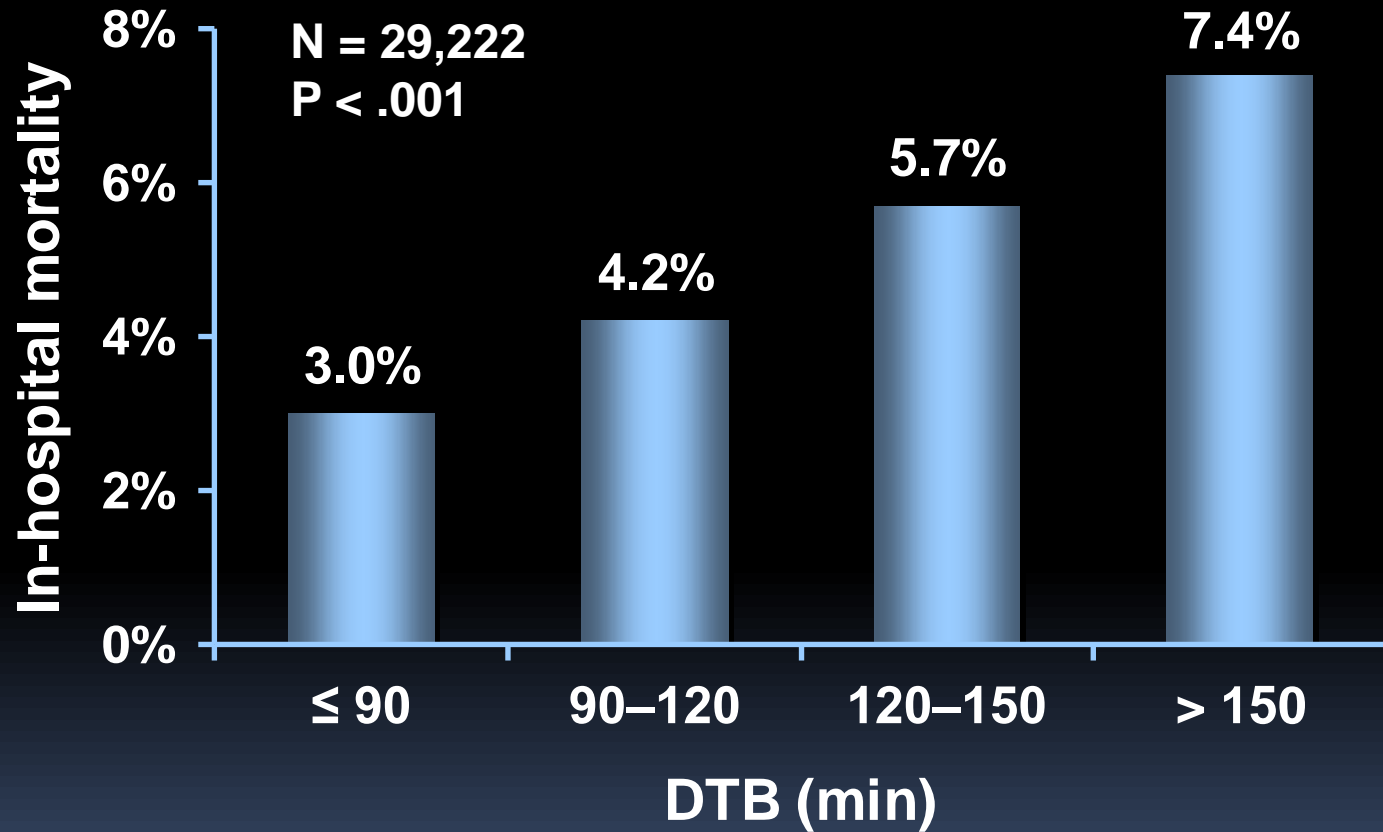
EMS transport directly to a PCI-capable hospital for primary PCI is the recommended triage strategy for patients with STEMI with an ideal FMC-to-device time system goal of 90 minutes or less.*

*The proposed time windows are system goals. For any individual patient, every effort should be made to provide reperfusion therapy as rapidly as possible.

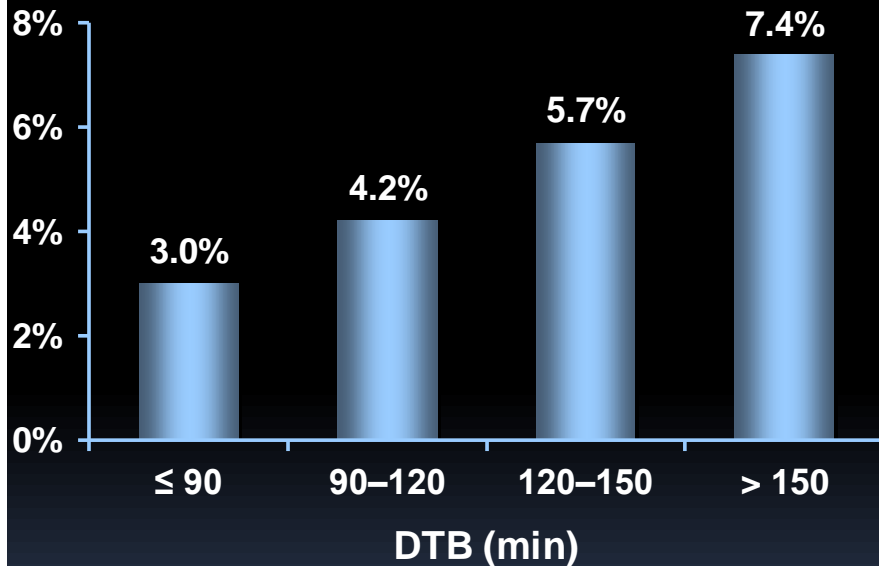
Primary PCI in STEMI

	COR	LOE
Ischemic symptoms <12 h	I	A
Ischemic symptoms <12 h and contraindications to fibrinolytic therapy irrespective of time delay from FMC	I	B
Cardiogenic shock or acute severe HF irrespective of time delay from MI onset	I	B
Evidence of ongoing ischemia 12 to 24 h after symptom onset	IIa	B
PCI of a noninfarct artery at the time of primary PCI in patients without hemodynamic compromise	III: Harm	B

D2B Times – Fantastic Gains in U.S.A. and Europe



Quantifying Value of 4.4% Reduction in AMI Mortality



4.4% reduction in mortality is achieved by responding immediately and improving D2B processes

This reduction in mortality is greater than use of all AMI drugs! Aspirin, Beta Blockers, Statins, ACEI

It is the single most effective way to reduce AMI mortality!

Perhaps, even reduce global mortality?

If you add to it the morbidity benefits, what procedure in medicine do you know that achieves such global improvement in life?

The Economics of Heart Attack: Mortality

- Puerto Rico 17,913 , population 3,897,960² (http://www.cureresearch.com/h/heart_attack/stats-country.htm)
- With a mortality rate of 18.6%, this equates to 3,332 deaths annually from AMI



Impact of STEMI Interventions on AMI

Incidence – 17,913

Mortality – 18.6% (3%)

Total mortality from AMI: 3,332 (537)

Annual 2,795 lives saved from STEMI



The Economics of Heart Attack: Morbidity

- Asymptomatic recovery : 25% or 4,493 patients (long term anti-platelets, statins, beta blockers)
- Mild to moderately symptomatic : 50% or 8,986 patients (statins, anti platelets, nitrates, beta blockers, ACE inhibitors)
- Severely symptomatic with ischemic cardiomyopathy : 25% or 4,493 patients (statins, anti platelets, nitrates, beta blockers, ACE/ARB and diuretics).



Impact of STEMI Interventions on Morbidity

- Group I: Asymptomatic recovery : 25% or 4,493 patients (long term anti-platelets, statins, beta blockers)
- Group II: Mild to moderately symptomatic : 50% or 8,986 patients (statins, anti platelets, nitrates, beta blockers, ACE inhibitors)
- Group III: Severely symptomatic with ischemic cardiomyopathy : 25% or 4,493 patients (statins, anti platelets, nitrates, beta blockers, ACE/ARB and diuretics)
- **STEMI Interventions have an ability to convert group II and group III to group I**



The Economics of Heart Attack: Morbidity

- Asymptomatic recovery : 25% or 4,493 patients (long term anti-platelets, statins, beta blockers) - \$1,000/year
- Mild to moderately symptomatic : 50% or 8,986 patients (statins, anti platelets, nitrates, beta blockers, ACE inhibitors) - \$ 20,000/year (2 hospitalizations/year)
- Severely symptomatic with ischemic cardiomyopathy : 25% or 4,493 patients (statins, anti platelets, nitrates, beta blockers, ACE/ARB and diuretics) - \$50,000/year (5 hospitalizations/year)



The Economics of Heart Attack: Morbidity

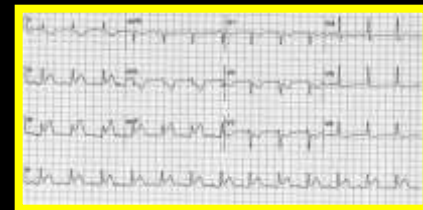
- Group 1, 4,493 patients, \$1,000/year : \$4.49 million/year
- Group II, 8,986 patients, \$ 20,000/year (2 hospitalizations/year, and/or PCI/CABG) : \$17.9 million/yr
- Group III, 4,493 patients, \$ 100,000/yr (5 hospitalization/year, and or PCI/CABG) : \$22.4 million/yr
- Converting group II and Group III to Group 1: annual saving of \$27.90 million/year



Global Perspective...

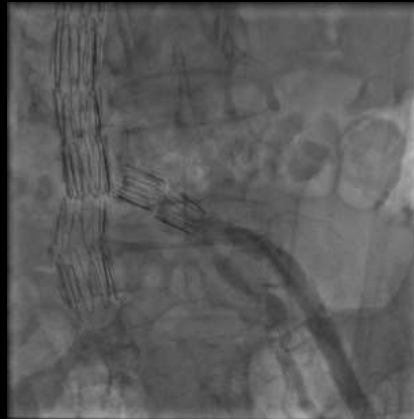
- Only 11% of world population can have Primary PCI
- In Puerto Rico, this fantastic procedure can be offered to the entire population
- As a result of the PRINCE program
- The ED group is a vital component of this unprecedented nationwide project!

“Process” & “Procedure” of STEMI Interventions



To improve D2B outcomes, it is critical to improve both
the Process and the Procedure

A STEMI Intervention is a blind date!



The only event that you control in the STEMI process is how quick you are -- to abandon immediately what you are doing and jump in your car!

Improving the STEMI “Process” - Train
the First Responders for Greatest
Efficiency



10 Best Strategies to Improve D2B Outcomes

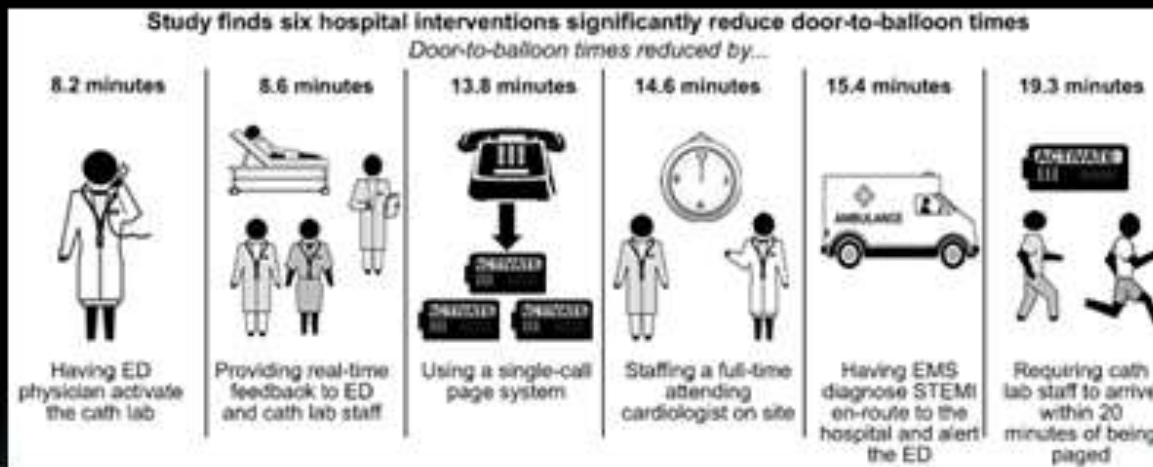
Improving Procedure

- 1. Culprit Lesion Identification & Parameters of success
- 2. Standardized techniques
- 3. Understanding thrombus dynamics/ Selective strategy for thrombus management
- 4. Intracoronary Vasodilators
- 5. Bivalirudin as default anti-coagulant
- 6. Glycoprotein 2b-3A inhibitors

Improving Process

- 1. STEMI system of care
- 2. Committed 24/7 D2B strategy
- 3. Pre Hospital Triage and Pre Hospital management
- 4. ED Bypass
- 5. Team Work

Effective Strategies



**“An ambulance system is the
currency with which you purchase
D2B times”**

*Sameer Mehta, MD.
SPAN, St. Petersburg, Russia, March 2012*

STEMI Management Center

The STEMI Management Center



- Immediate STEMI Diagnosis with 12 leads EKG.
- Wireless Transmission.
- Medical Stabilization.
- STEMI Pharmacology.
- Manage Complications
- Educate Patient.



PRINCE – MISSION STATEMENT

To leave a legacy of quality healthcare for the citizens of Puerto Rico by creating a world-class, population-based system of the management of acute myocardial infarction





2013 EXECUTIVE COMMITTEE

Fernando Lapetina, MD PRINCE Chairperson

Orlando Rodriguez Vila MD and Sameer Mehta MD Co-chairs

Miguel Campos MD MD Past PRINCE Chair, Champion, Metro-Pavia Hospital

Manuel Areces and Jose Novoa MD Champions, CCPRC

Carlos Nieves, MD Champion, HIMA-San Pablo Hospital

Edgardo Bermudez, MD Champion, Hospital San Lucas

Efrain Feliciano Champion, Auxilio Mutuo Hospital

Jose Escabi, MD Champion, VA Medical Center

Juan Zevallos, PhD Data Management Center

Lumen Foundation STEMI Initiatives



★ STEMI Education/Lectures

● Lumen International Conference

★ Population Based STEMI Programs

Pillars of PRINCE

- **Pillar #1: Hospital D2B-reducing processes**
 - Implement known effective strategies
 - Continuous quality improvement
- **Pillar #2: Pre-hospital strategies**
 - EMS pre-hospital diagnosis and triage
 - Pre-hospital cath lab activation
- **Pillar #3: Tackle total ischemia time**
 - Educate patients about warning signs
 - Improve 911/EMS utilization

Core Requirements to Build a STEMI Program

- 24/7 Cath Lab availability:
 - Cath Lab staff
 - Interventional cardiologist
- On-site cardiothoracic surgery
- Appoint a Physician champion
- Appoint a STEMI coordinator

Key STEMI-PCI Process Strategies

- ER MD activates the Cath Lab
- Single-call to central operator
- STEMI-PCI team expected arrival <20 to 30 min.
- Data monitoring and prompt feedback to ER and Cath Lab staff
- Organizational support for sustainable change
- Team-based approach and continuous quality improvement

Pillars of PRINCE

- Pillar #1: Hospital D2B-reducing processes
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PRINCE-EMS
Task Force

Challenges and Solutions: Goals for 2013 through 2014

- Pillar #1: Hospital D2B-reducing processes
 - Implement known effective strategies
 - Continuous quality improvement
- **Pillar #2: Pre-hospital strategies**
 - EMS pre-hospital diagnosis and triage
 - Pre-hospital cath lab activation
- **Pillar #3: Tackle total ischemia time**
 - Educate patients about warning signs
 - Improve 911/EMS utilization

PRINCE Quality Elements (continued)

- EMS core quality elements (6) to facilitate pre-hospital diagnosis and triage
 1. 12 lead ECG capability
 2. Wireless transmission capability
 3. GPS enabled for routing
 4. Paramedics trained in STEMI ECG recognition
 5. Paramedics trained in initial pharmacotherapy
 6. Triage and transfer algorithm aided by dispatch center

STEMI Centers in Puerto Rico



10 miles - Scale



PRINCE – Tasks Accomplished

- Leadership, Organization, Partners, Stakeholders
- Integration of San Juan PCI centers
- Standardized protocol, consent, database
- Effective STEMI standard operating procedures with single page, strict on call, STEMI champions
- Very close EMS partnership & trust
- Lives saved, daily
- Firm culture of STEMI Interventions
- Education of PR cardiologists, physicians.

**MEAN TIME
D₂B
PACIENTES RECIBIDOS POR SALA DE EMERGENCIA**

CRITERIOS	JULIO 2010 DATABASE	SEPT A DIC 2010	ENERO A DIC 2011	ENERO A DIC 2012	ENERO A DIC 2013	ENERO A MARZO 2014
Total de casos evaluados e identificados	2	14	32	43	56	13
Tiempo de llega a EKG	115/2=57.2	181/14=12.9 mins.	242/30=8.0 mins (2 EKG en el momento que presente dolor)	341/41=8 mins. (2 EKG en el momento que present dolor)	387/53=7.3 mins. (3 EKG en el momento presentó dolor)	132/13=10 mins.
EKG activar equipo	195/2=97.5	946/14=67.5 mins.	806/32=25.1	859/43=20 mins.	1652/56=29.5 mins.	142/13=10.9 mins.
xD ₂ B-	469/2=234.5 mins.	1262/9=140.2 mins. (2 SO, 2 cateterismo, 1 fallece)	3708/30=123.6 mins. (hrs. laborables)	3838/43=89 mins.	4721/56=84.3 mins.	1024/13=78.7 mins.
D ₂ B <90 mins.	0	3/9 = 33%	16/30 = 53%	30/43 = 70%	48/56=78%	9/13=69%

D₂B STEMI
Análisis de Tiempo
PACIENTES RECIBIDOS POR SALA DE EMERGENCIA
2014


CRITERIOS	enero	febrero	marzo	abril	mayo	junio
Total de casos evaluados e identificados	5	6	2	3	4	4
Tiempo de obtener el EKG	44/55=8.8 min.	45/6=7.5 mins.	43/2=21.5 min.	39/3=13 min.	4/4=1 min.	12/3=4 min.
Tiempo que toma entre EKG y notificar al Cardiólogo	53/5=10.6	78/6=13 mins.	11/2=5.5 mins.	31/3=10 mins.	96/4=24 mins	39/3=13 mins
Tiempo respuesta personal de Laboratorio Cardiovascular	110/04=27.5 mins. (1 hora laborable)	66/4=16.5 mins. (2 horas laborables)	26/1=26 mins. (1 hora laborable)	50/2=25 mins. (1 hora laborable)	30/1=30 mins. (3 horas laborables)	66/3=22 mins.
Tiempo Total Sala de Emergencia	230/5=46 mins	316/6=52.6 mins.	96/2=48 mins.	152/3=50.6 mins.	182/4=45.5 mins.	167/3=55.6 mins.
Tiempo Laboratorio Cardiovascular	198/5=36.6	156/6=26 mins.	28/2=14 mins.	73/3=24.3 mins.	114/4= 28.5 mins.	92/3=30.6 mins.
Tiempo desde llegada a primera dilatación	428/5=85.6 mins.	472/6=78.6 mins.	124/2=62 mins.	225/3=75 mins.	296/4=74 mins.	259/3=86.3 mins.
Casos no identificados	0	0	1	0	0	0
% pacientes realizados ≤ 90 minutos	3/5=60%	4/6=67%	2/2=100%	3/3=100%	3/4=75%	2/3=67%

D₂B STEMI
Análisis de Tiempo
PACIENTES RECIBIDOS TRANSLADADOS
2014

CRITERIOS	enero	febrero	marzo	abril	mayo	junio
Total de casos evaluados e identificados	7	9	9	5	6	7
Tiempo respuesta personal de Laboratorio Cardiovascular	72/5=14.4 mins. (2 horas laborables)	105/5=21 mins. (4 horas laborables)	141/6=23.5 mins. (3 horas laborables)	71/3=23.6 mins. (2 horas laborables)	10/1=10 mins. (4 horas laborables 1 team ya activado)	56/3=18.6 mins. (4 horas laborables)
Tiempo Total Sala de Emergencia	230/5=46 mins	316/6=52.6 mins.	96/2=48 mins.	152/3=50.6 mins.	182/4=45.5 mins.	167/3=55.6 mins.
Tiempo desde llegada a primera dilatacion	192/7=27.4 mins.	375/9=41.6 mins.	395/9=43.8 mins.	179/5=35.8 mins.	282/6=47 mins.	206/7=29.4 mins.
% pacientes realizados ≤ 90 minutos	7/7 100%	9/9 100%	8/9 89%	5/5 100%	4/5 80%	7/7 100%



PRINCE, the landmark AMI Project


- Absolutely unique – in size, dimension & ambition
 - Huge advancement over STEMI system of care programs
 - Template for global AMI population-based programs
 - Fantastic partnership between stake holders with a mission to improve AMI care.
- 

Top 10 Gains of PRINCE...

- 1. EMS
- 2. Cultural change
- 3. Nationwide 24/7 STEMI
- 4. Administrative support
- 5. ACC partnership
- 6. Abbott Vascular alliance
- 7. Team work
- 8. Leadership
- 9. STEMI champions
- 10. Inclusiveness



Challenges Ahead...

- Harness the full potential of Centro Cardiovascular
 - Advance Ponce to the level of San Juan
 - Develop Mayaguez
 - Streamline EMS (designate STEMI ambulances, unambiguous roles for city and private ambulances, wireless transmission)
 - Optimize data capture
 - Political patronage/press & media
 - Broaden stake holders
 - Public education
 - Publications
 - Living History Educational Document for ACC.
- 



Conclusions...

- We need the whole hearted support of ED physicians
- PRINCE will make great strides with ED/EMS integration
- We solicit your support for leaving a legacy for Puerto Rico!