



The BEST TRIP Trial*

Intracranial pressure monitoring in severe traumatic brain injury: A randomized trial

Chesnut RM, Temkin N, Carney N, Dikmen S, Rondina C, Videtta W, Petroni G, Lujan S, Pridgeon J, Barber J, Machamer J, Chaddock K, Celix JM, Cherner M. and Hendrix T

for the Global NeuroTrauma Research Group

Benchmark **E**vidence from **S**outh American **T**rials:
TReatment of **I**ntracranial **P**ressure

The UW Latin American TBI Project

Two emb

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PRCT on the influence of monitor driven treatment of intracranial pressure (ICP), versus that based on clinical and imaging studies, on the outcome from severe TBI

ICP monitoring and ICP-monitor-based treatment
heralded the modern era of sTBI management



50+% Mortality



36-18% Mortality

Ventilator Management

F.E.N.

Critical Care



Changed
"surgical vs non-surgical"
to "all patients treatable"

Ancillary
Monitoring

Intensivist
Involvement

ICU
Nursing

Infectious
Disease

Advances in Rehabilitation

Improvements in Imaging

Development of Trauma Surgery

Advances in Emergency Care

Advances in Prehospital Care

Ventilator Management

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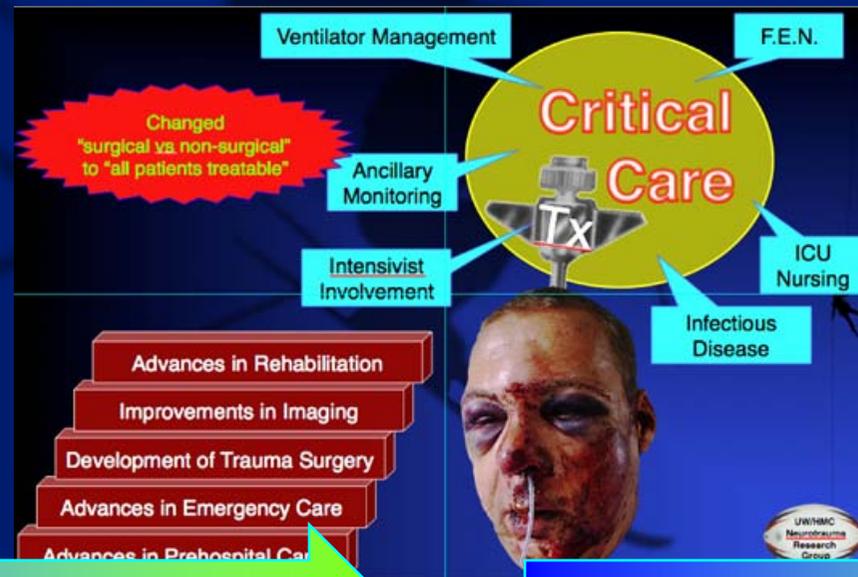
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Advances in Emergency Care

Advances in Prehospital Care



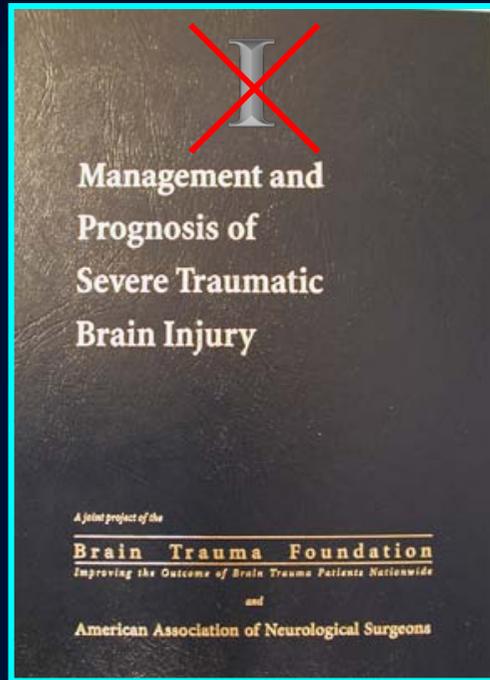
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II



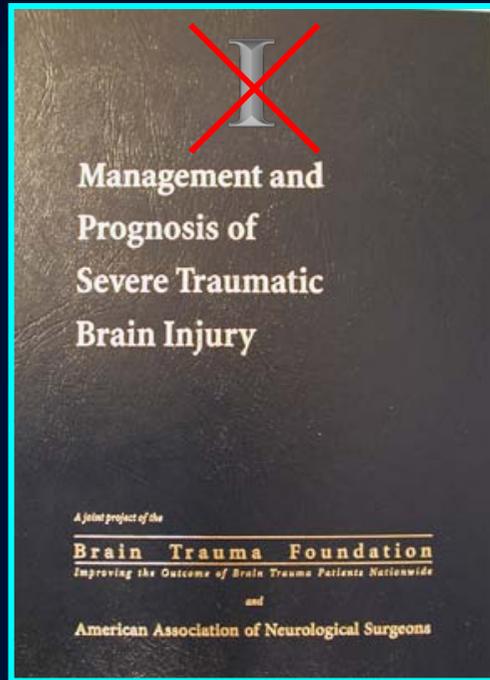
III

Need for a
Class I
study

“For ethical reasons, it is unlikely that an RCT on ICP monitoring will ever be done*”

“ICP-Less” Control

II



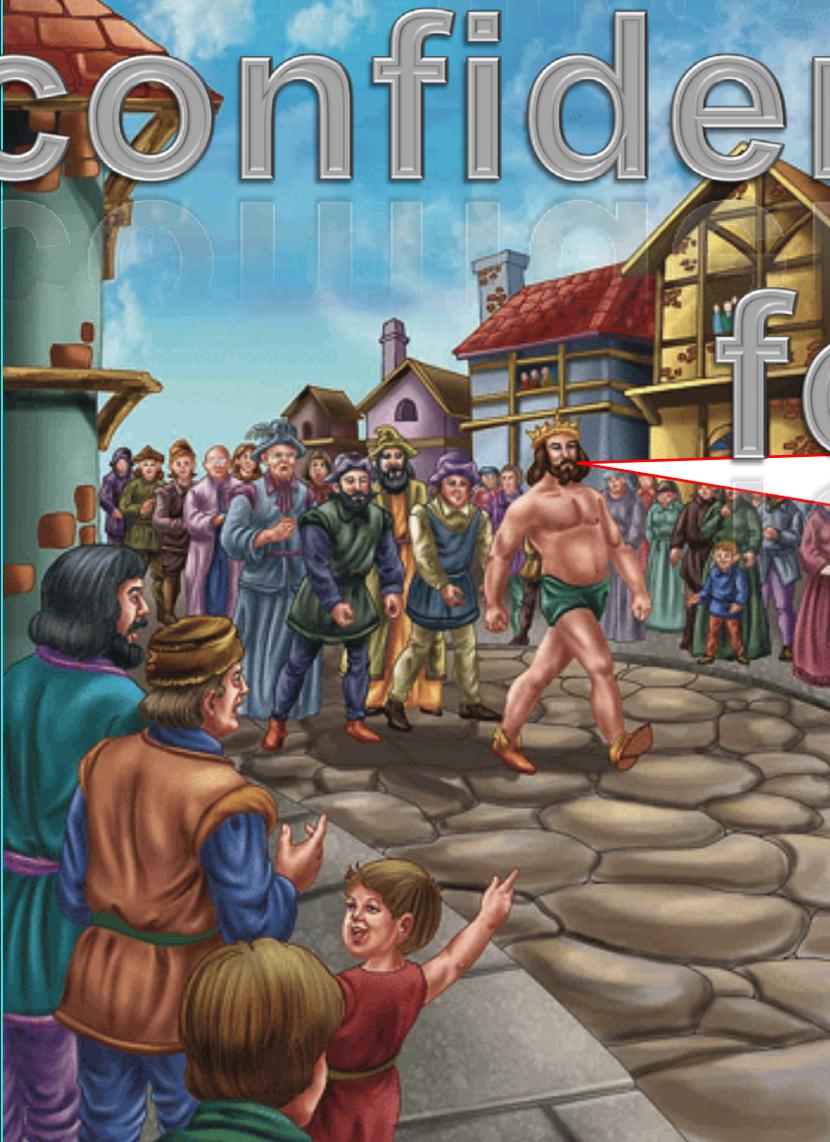
III

Need for a
Class I
study

“For ethical reasons, it is unlikely that an RCT on ICP monitoring will ever be done*”

“Equipose” Covered!

Nothing destroys
confidence like
follow-up!



¿Just what needs
proving about ICP?

General Overview

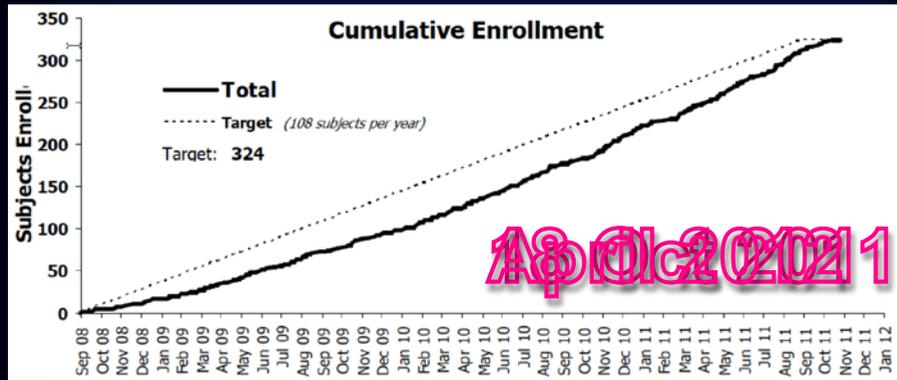
ICP RCT

- Multicenter, two-parallel-group stratified (site, severity, age) design with equal randomization
 - Patients = sTBI patients ($GCS \leq 8$)
 - Comparing 2 protocolised treatments
 - ICP Group - ICP treatment followed the BTF Guidelines
 - ICE Group - ICP treatment based on imaging & clinical exam
 - Primary outcome
 - Composite outcome score
 - Intent-to-treat analysis

This study was approved by the University of Washington IRB and FWA-approved ethics committees at all centers.



Randomised Controlled ICP Trial



★ Santa Cruz de la Sierra, Bolivia

★ Santa Cruz de la Sierra, Bolivia

★ Cochabamba, Bolivia

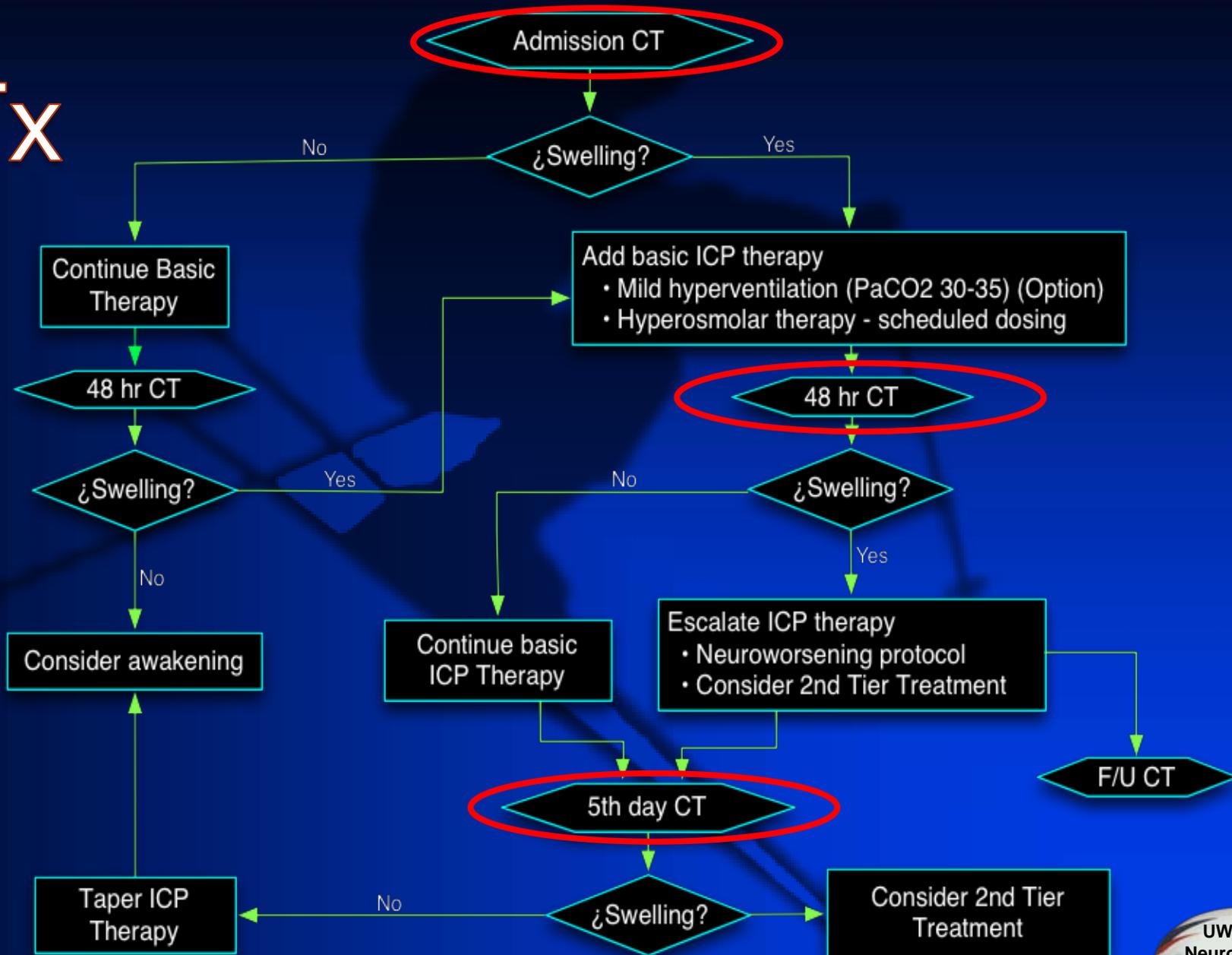
★ Tarija, Bolivia

★ Guayaquil, Ecuador

★ Quito, Ecuador



ICE Tx



Primary ICE Treatment for Cerebral Edema

Mild hyperventilation

- Maintain PaCO₂ 30-35 mmHg (28-32 mmHg in Cochabamba)

Hyperosmolar/Hypertonic Therapy

- Mannitol used first except with hypotension, hypovolaemia, or hyponatraemia
 - Mannitol guidelines and dosing
 - Suspend for plasma osmolarity > 320 or tonicity > 340
 - Mannitol dosing regimen (20% Mannitol bolus):
 - 100ml (20gm) IV every 3-4 hours for the first 3 days, then
 - 80ml (16gm) IV every 3-4 hours on day 4, then
 - 60ml (12gm) IV every 3-4 hours on day 5, then
 - 40ml (8gm) IV every 3-4 hours on day 6 and suspend
 - Hypertonic saline guidelines and dosing
 - Suspend for plasma osmolarity > 360 or tonicity > 380 or serum Na > 160
 - Hypertonic saline dosing regimen (5%NaCl solution bolus):
 - 100ml IV 5% NaCl solution every 4-12 hours x 6 d then suspend

CSF drainage as an option requiring separate placement of EVD

Composite Primary Outcome Measure

Outcome measure variables in the primary composite

- Mortality
- Time to follow commands
 - Injury through GCSm = 6
- Sum of Errors on the GOAT
- Functional status at 3 and 6 months
 - GOS-E
 - DRS
- Neuropsychological assessment
 - Tests translated, adapted, & normed in mono-lingual Spanish speakers by Drs. Robert Heaton and Mariana Cherner

General
Mortality
Time
GOAT

Mental status

- Mini-Mental Status Exam

Working memory

- PASAT

Information processing speed

- WAIS III Digit Symbol
- WAIS III Symbol Search
- Colour Trails, Pt 1

Learning & recall

- Spanish Verbal Learning Test
- Brief Visuospatial Memory Test Revised

Executive functioning

- Executive Functioning
- Trail Making Test (Parts A & B)
- Phon Fluency (Actions)
- FOWAT
- Colour Trails, Pt 2

Motor speed & dexterity

- Grooved Pegboard Test

Treated examiners blinded to assigned Tx administered the 3- & 6-month outcome measures in the participant's primary language

Scores converted to percentiles to account for missing values

- Mortality assigned worst score values

Scores equally weighted in analysis

GOAT = Galveston Orientation Amnesia Test
 GOS-E = Glasgow Outcome Scale – Extended
 Drs = Disability Rating Scale

Power Analysis

The sample size was determined to provide 80% power to detect a 10-percentage point increase in the percent with good outcome or moderate disability

Rationale for composite measure

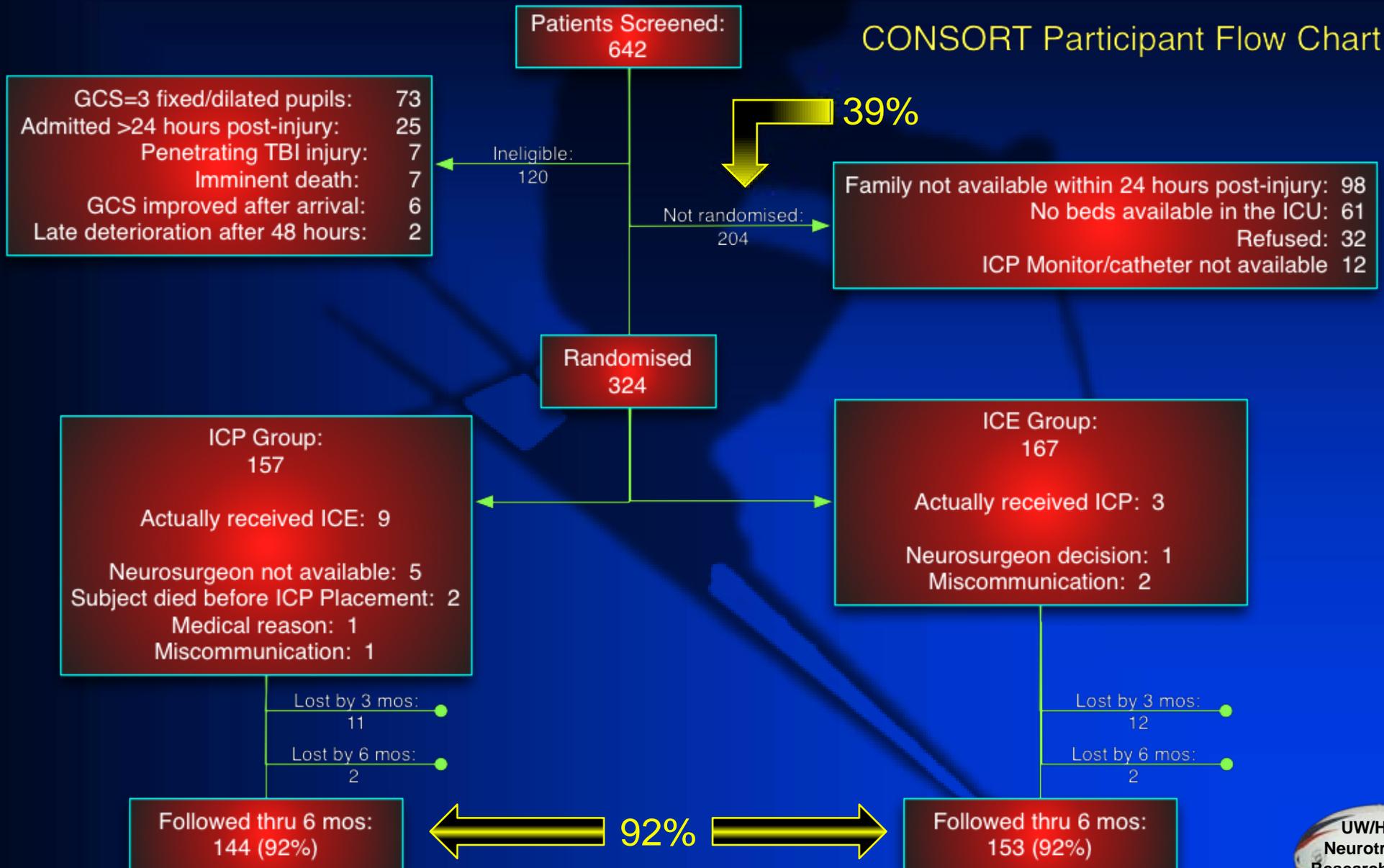
- GOS-E has excellent validity
 - Dichotomous version requires ca. 800 cases for this power
- Composite score is more sensitive to such outcomes
 - Requires only 324 cases

Results

Results

September 2008 and October 2011

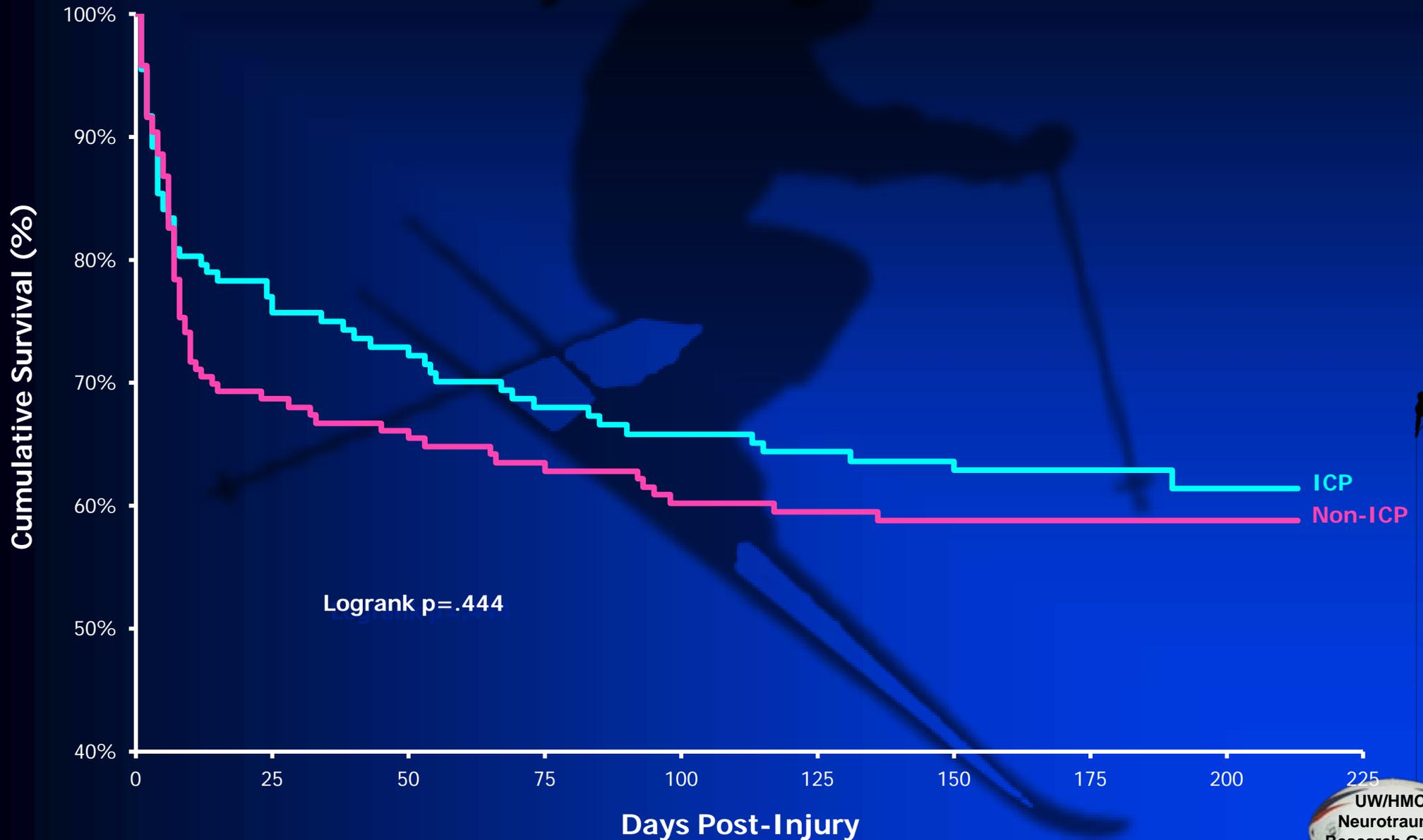
CONSORT Participant Flow Chart



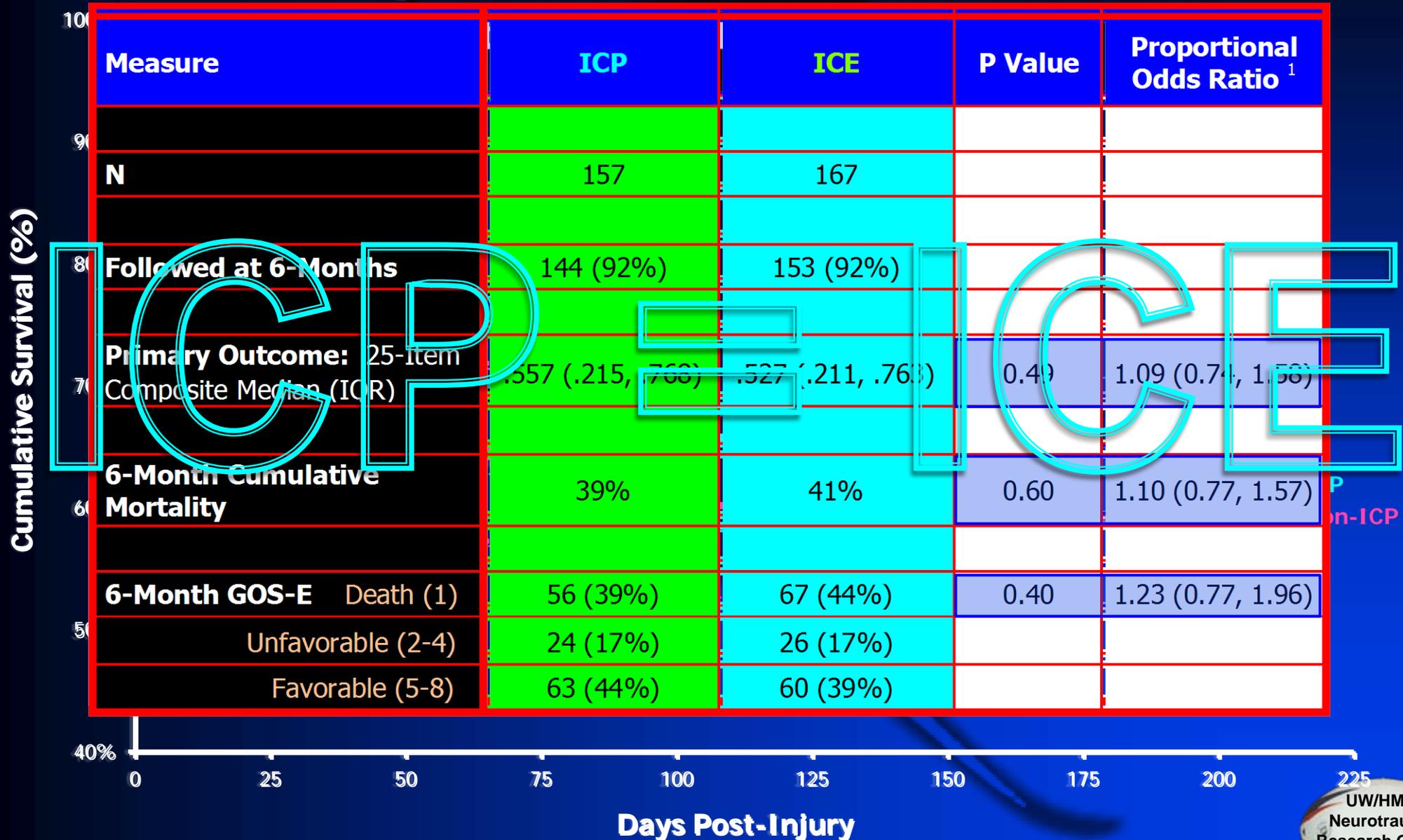
Pre-specified Primary Outcome

Measure	ICP	ICE	P Value	Proportional Odds Ratio ¹
N	157	167		
Followed at 6-Months	144 (92%)	153 (92%)		
Primary Outcome: 25-Item Composite Median (IQR)	.557 (.215, .768)	.527 (.211, .763)	0.49	1.09 (0.74, 1.58)
6-Month Cumulative Mortality	39%	41%	0.60	1.10 (0.77, 1.57)
6-Month GOS-E				
Death (1)	56 (39%)	67 (44%)	0.40	1.23 (0.77, 1.96)
Unfavorable (2-4)	24 (17%)	26 (17%)		
Favorable (5-8)	63 (44%)	60 (39%)		

Mortality Through 7 Months



Pre-specified Outcome Results



Pre-specified Secondary Outcomes

Measure	All Randomized Cases			
	ICP	ICE	P Value	Proportional Odds Ratio
N	157	167		
Protocol-specified comparisons				
ICU LOS (Days) Median (IQR)	12 (6, 17)	9 (6, 16)	.25	0.81 (0.55, 1.18)
ICU LOS as Brain-specific Treatment (Days) Median (IQR)	3.4 (1.1, 7.0)	4.8 (2.3, 7.4)	.002	1.87 (1.28, 2.75)
Complications				
Respiratory Complications	93 (59%)	108 (65%)	.36	1.00 (0.63, 1.59)
Sepsis	16 (10%)	12 (7%)	.43	0.61 (0.27, 1.41)
Decubitus Ulcers	19 (12%)	8 (5%)	.03	0.35 (0.15, 0.85)
Non-Neurological Complications	134 (85%)	147 (88%)	.52	1.20 (0.62, 2.34)

Combined Secondary Outcomes

Measure	All Randomized Cases			
	ICP	ICE	P Value	Proportional Odds Ratio
N	157	167		
Protocol-specified comparisons				
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Non-Neurological Complications	134 (85%)	147 (88%)	.52	1.20 (0.62, 2.34)
Post-hoc comparisons				
Integrated Brain-Specific Treatment Intensity Median (IQR)	69 (13, 181)	125 (45, 233)	<.001	2.36 (1.60, 3.47)
Barbiturates	38 (24%)	22 (13%)	.02	0.46 (0.25, 0.83)
Neurosurgical Procedures				
Craniotomy for mass lesion	63 (40%)	74 (45%)	.50	1.19 (0.76, 1.86)
Craniectomy	44 (28%)	49 (30%)	.81	1.04 (0.63, 1.69)
Craniectomy alone	9 (6%)	9 (5%)	1.00	0.93 (0.35, 2.42)
Craniectomy with other NS	35 (22%)	40 (24%)	.79	1.07 (0.63, 1.80)

Implications

Implications

Generalisation

Internal validity

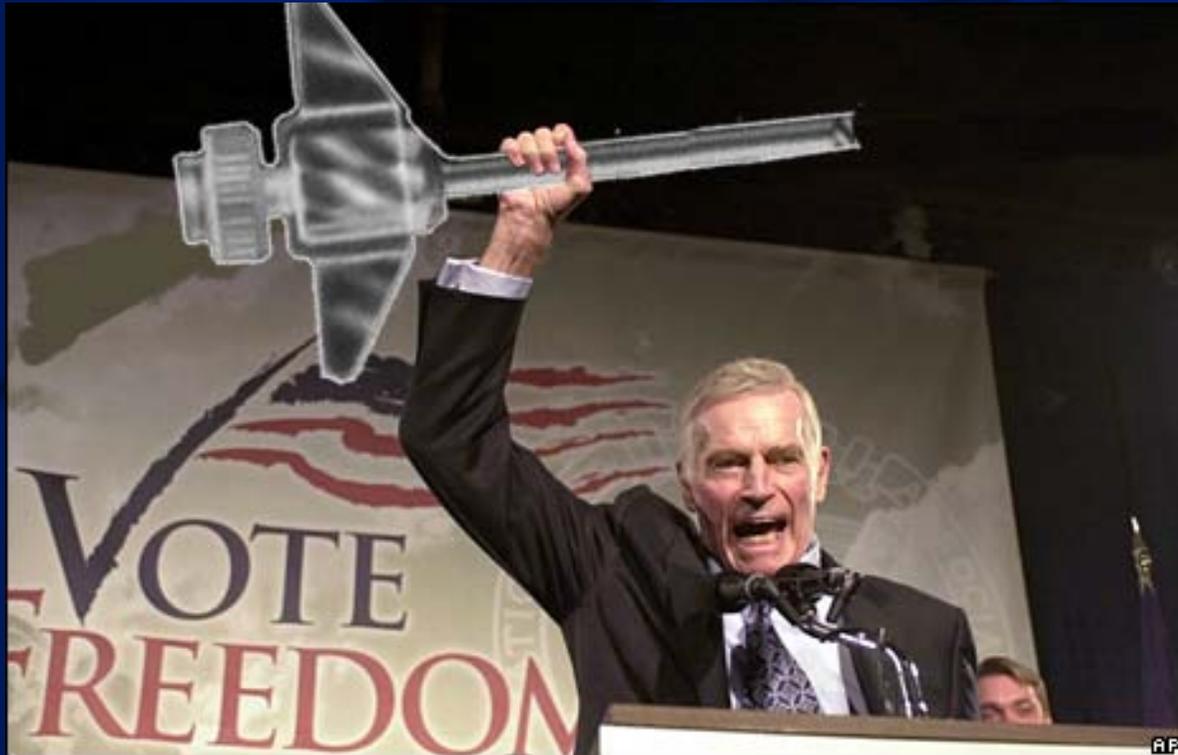
- High compliance with study design
- High level of ICU care
- High IRR on diagnostic and follow-up measures
- 92% follow-up
- This study accurately represents reality in LA and LMIC's

Generalisation

External validity

- Good for generalisation to HIC's within frame of ICU care
 - ICU admission through ICU discharge
- Caution when generalising to all pre-hospital sTBI patients
 - Less well developed and organised
 - Pre-admission attrition ¿balanced? by increased SBI's?
 - **Unsuccessful in gathering quality data on this epoch**
- Caution when generalising to the post-ICU-discharge period
 - Minimal medical care, minimal F/U, no rehabilitation
 - Same care environment for ICP and ICE groups
 - ¿Influence on generalisability to HIC's?

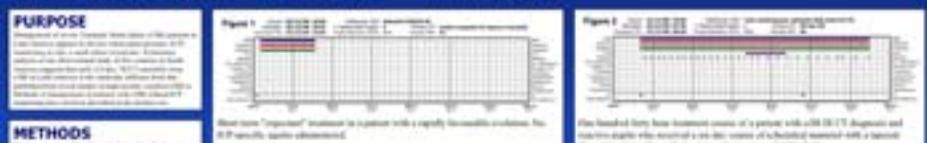
Can this study “kill” ICP monitoring



ICP monitors don't kill people;
mismanagement kills people

P313 Patterns of ICP Management in Severe Traumatic Brain Injury Patients in the Absence of ICP Monitoring in Latin America

W. Videtta¹, MD; C. Rondina¹, MD; S. Lujan¹, MD; G. Petroni¹, MD, MCR; N. Temkin¹, PhD; J. Celix¹, MD; S. Dikmen¹, PhD; J. Barber¹, MS; J. Machamer¹, MA; J. Pridgeon¹, MHA; K. Chaddock¹, BA; R. Chesnut¹, MD, FCCM, FACS
 1 Latin American Brain Injury Consortium, Argentina



PURPOSE
 The Latin American Pilot Traumatic Coma Data Bank (LATPCDB) is a prospective, multicenter study designed to evaluate the effectiveness of ICP monitoring in severe traumatic brain injury (TBI) patients in Latin America. The study aims to determine the impact of ICP monitoring on patient outcomes, including mortality and disability.

METHODS
 The study included patients with severe TBI who were enrolled in the LATPCDB. Data on ICP management, including the use of ICP monitoring, was collected. Outcomes were measured in terms of mortality and disability.

RESULTS
 The study found that ICP monitoring was used in a significant number of patients. The use of ICP monitoring was associated with improved outcomes, including lower mortality and disability rates.

Patient/Injury Characteristics

Characteristic	Number	Percentage
Age (Mean ± SD)	38.5 ± 15.2	
Gender (Male/Female)	112/88	56.0%/44.0%
ICP Monitoring (Yes/No)	150/140	52.0%/48.0%
Mortality (Yes/No)	180/170	51.4%/48.6%
Disability (Yes/No)	220/150	59.5%/40.5%

P311 Prognosis in Severe Traumatic Brain Injury Cross Validation of Predictive Models Using Latin American Data Base

G. Petroni¹, MD, MCR; P. Perini¹, MD; C. Rondina¹, MD; W. Videtta¹, MD; S. Luján¹, MD; J. Pridgeon¹, MHA; J. Celix¹, MD; J. Machamer¹, MA; J. Barber¹, MS; K. Chaddock¹, BA; R. Chesnut¹, MD, FCCM, FACS
 1 Latin American Brain Injury Consortium, Argentina

RESULTS - Statistics

Model	Accuracy	Precision	Recall	F1 Score
Model 1	0.75	0.80	0.70	0.75
Model 2	0.70	0.75	0.65	0.70
Model 3	0.72	0.78	0.68	0.72
Model 4	0.73	0.79	0.69	0.73
Model 5	0.74	0.80	0.70	0.74

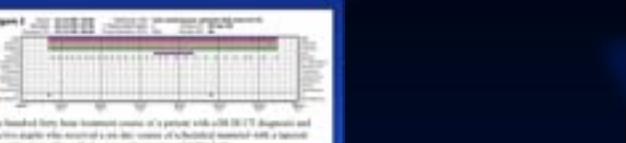
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OBJECTIVES
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METHODS
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P310 Outcome From Severe Traumatic Brain Injury in Latin America: Results from the Latin American Pilot Traumatic Coma Data Bank

R. Chesnut¹, MD, FCCM, FACS; J. Celix¹, MD; K. Chaddock¹, BA; S. Dikmen¹, PhD; S. Lujan¹, MD; G. Petroni¹, MD, MCR; J. Pridgeon¹, MHA; C. Rondina¹, MD; N. Temkin¹, PhD; J. Barber¹, MS; J. Machamer¹, MA; W. Videtta¹, MD
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P312 ICP Monitoring and Outcome From Severe Traumatic Brain Injury in Latin America

G. Petroni¹, MD, MCR; P. Perini¹, MD; C. Rondina¹, MD; W. Videtta¹, MD; S. Luján¹, MD; J. Pridgeon¹, MHA; J. Celix¹, MD; J. Machamer¹, MA; J. Barber¹, MS; K. Chaddock¹, BA; R. Chesnut¹, MD, FCCM, FACS
 1 Latin American Brain Injury Consortium, Argentina

RESULTS

ICP Monitoring	High Resource	Low Resource	Total
Yes	150 (52.0%)	140 (48.0%)	290 (52.0%)
No	140 (48.0%)	150 (52.0%)	290 (48.0%)
Total	290 (52.0%)	290 (48.0%)	580 (50.0%)

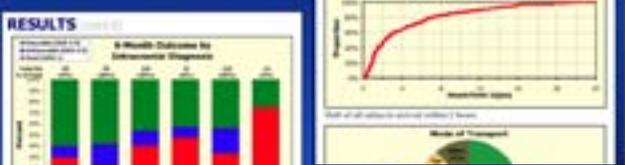
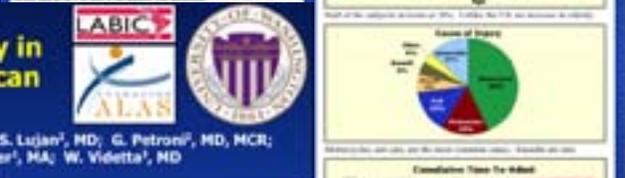
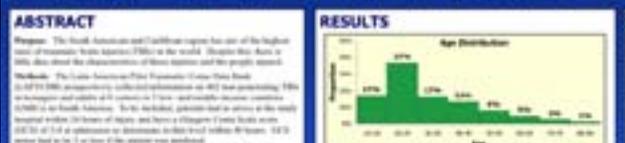
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P314 Latin American Pilot Traumatic Coma Data Bank: Baseline Characteristics

N. Temkin¹, PhD; S. Lujan¹, MD; G. Petroni¹, MD, MCR; C. Rondina¹, MD; W. Videtta¹, MD; S. Dikmen¹, PhD; J. Barber¹, MS; J. Machamer¹, MA; J. Celix¹, MD; J. Pridgeon¹, MHA; K. Chaddock¹, BA; R. Chesnut¹, MD, FCCM, FACS
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CONCLUSIONS
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P315 ICP Monitoring and Outcome From Severe Traumatic Brain Injury in Latin America

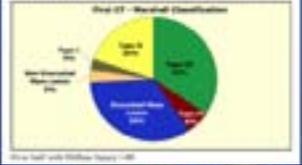
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Gender (Male/Female)	112/88	112/88	224/176
ICP Monitoring (Yes/No)	150/140	150/140	300/280
Mortality (Yes/No)	180/170	180/170	360/340
Disability (Yes/No)	220/150	220/150	440/300

6-Month Outcomes by Resource Level

Resource Level	High Resource	Low Resource	Total
ICP Monitoring	150 (52.0%)	140 (48.0%)	290 (52.0%)
Mortality	180 (51.4%)	170 (48.6%)	350 (51.4%)
Disability	220 (59.5%)	150 (40.5%)	370 (59.5%)



ABSTRACT
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Patterns of ICP Management in Severe Traumatic Brain Injury Patients in the Absence of ICP Monitoring in Latin America

W. Valdesa, MD; C. Rondina, MD; ... MD, MCR; K. Tomlin, PhD; J. Colla, MD; S. Dikmen, PhD; J. Barber, MD; J. Machamer, MD; ... BA; B. Chesnut, MD, FCCM, FACS

PURPOSE

METHODS

RESULTS



OPEN MENU

10TH ANNUAL

NEUROCRITICAL CARE SOCIETY MEETING

REALIZING THE VISION



CONGRESS OF NEUROLOGICAL SURGEONS

2012 ANNUAL MEETING

OUR FUTURE IS NOW!

CHICAGO, ILLINOIS OCTOBER 6-10, 2012

Ninth World Congress on Brain Injury

Edinburgh, Scotland

March 21-25, 2012

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Hacia la integración y la multidisciplinaria

JINI 2012

- III JORNADAS INTERNACIONALES DE ENFERMERIA EN NEUROINTENSIVISMO
- II JORNADAS INTERNACIONALES DE KINESIOLOGIA EN NEUROINTENSIVISMO
- I JORNADAS INTERNACIONALES DE EMERGENCIAS NEUROLOGICAS
- I JORNADAS INTERNACIONALES DE NUTRICION EN NEUROINTENSIVISMO

20 al 23 de junio de 2012
Círculo Oficiales de Mar - Buenos Aires - Argentina



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 Silvia Lujan, MD¹¹
 Juan Machamer, MEd¹²
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 Carlos Rondina, MD¹⁴
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Traumatic Brain Injury in Latin America: Lifespan Analysis Randomized Control Trial Protocol*

BACKGROUND: Although in the developed world the intracranial pressure (ICP) monitor is considered the standard of care for patients with severe traumatic brain injury (TBI), its usefulness to direct treatment decisions has never been tested rigorously.

OBJECTIVE: The primary focus was to conduct a high-quality, randomized, controlled trial to determine whether ICP monitoring used to direct TBI treatment improves patient outcomes. By providing education, equipment, and structure, the project will enhance the research capacity of the collaborating investigators and will foster the collaborations established during earlier studies.

METHODS: Study centers were selected that routinely treated ICP based on clinical examination and computed tomography imaging using internal protocols. We randomized patients to either an ICP monitor group or an imaging and clinical examination group. Treatment decisions for the ICP monitor group are guided by ICP monitoring based on established guidelines. Treatment decisions for the imaging and clinical examination group are made using a single protocol derived from those previously being used at those centers.

EXPECTED OUTCOMES: There are 2 study hypotheses: (1) patients with severe TBI whose acute care treatment is managed using ICP monitors will have improved outcomes and (2) incorporating ICP monitoring in the care of patients with severe TBI will minimize complications and decrease length of intensive care unit stay.

DISCUSSION: This clinical trial tests the effectiveness of a management protocol based on technology considered pivotal to brain trauma treatment in the developed world: the ICP monitor. A randomized, controlled trial of ICP monitoring has never been performed—a critical gap in the evidence base that supports the role of ICP monitoring in TBI care. As such, the results of this randomized, controlled trial will have global implications regardless of the level of development of the trauma system.

Neurosurgery 01-1-8, 2012 DOI: 10.1227/NEU.0b113w1107276b7 www.neurosurgery-online.com

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 Hospital Japonés, Santa Cruz de la Sierra site; P. Dr. Gustavo La Fuente Zolaín, gustavo@hospital.com
 Madras Hospital, Cochabamba site; P. Dr. Amaro Leonardo Cuellar, alev@hospital.com
 San Juan de Dios Hospital, Tarija site; P. Dr. H. Roberto Merlo Maldonado, robertom@hospital.com
 Country coordinator, La Paz: Freddy Sardi Lora, freddy@hospital.com

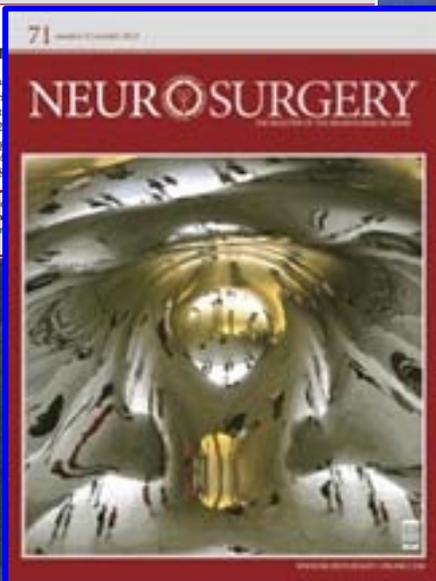
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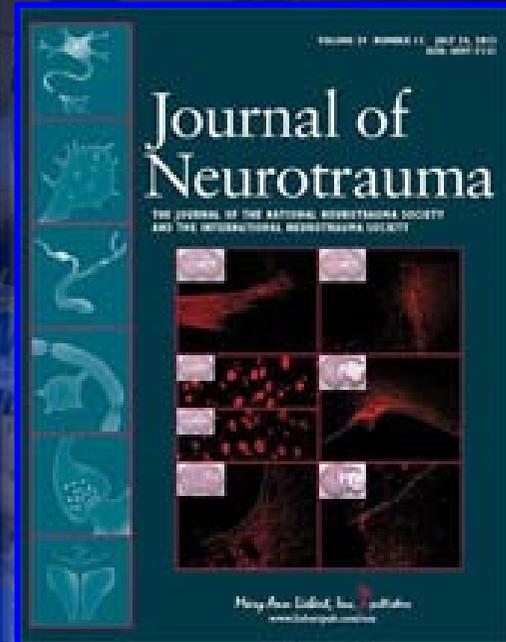
GENERAL INFORMATION

BEST TRIP (Benchmark South American Trauma)
 Intracranial Pressure
 Overall study dates: April 2011 to April 2012
 Funding agency: NIH/Fox Center/National Institute of Health and Stroke R01 NS058058

ABBREVIATIONS: GSC, Glasgow intracranial pressure; ICP, intracranial pressure; TBI, traumatic brain injury; Washington



+6



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Intracranial Pressure Monitoring in Severe Traumatic Brain Injury in Latin America: Process and Methods for a Multi-Center Randomized Controlled Trial

Nancy Carney,¹ Silvia Lujan,² Sureyya Dikmen,³ Nancy Temkin,³ Gustavo Petroni,² Jim Pridgeon,³ Jason Barber,³ Joan Machamer,³ Mariana Cherner,⁴ Kelley Chaddock,³ Terence Hendrix,⁴ Carlos Rondina,² Walter Videtta,⁵ Juanita M. Celix,³ and Randall Chesnut³





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210 NOTICE

010 CORRECTION

011 CONTINUED MEDICAL EDUCATION

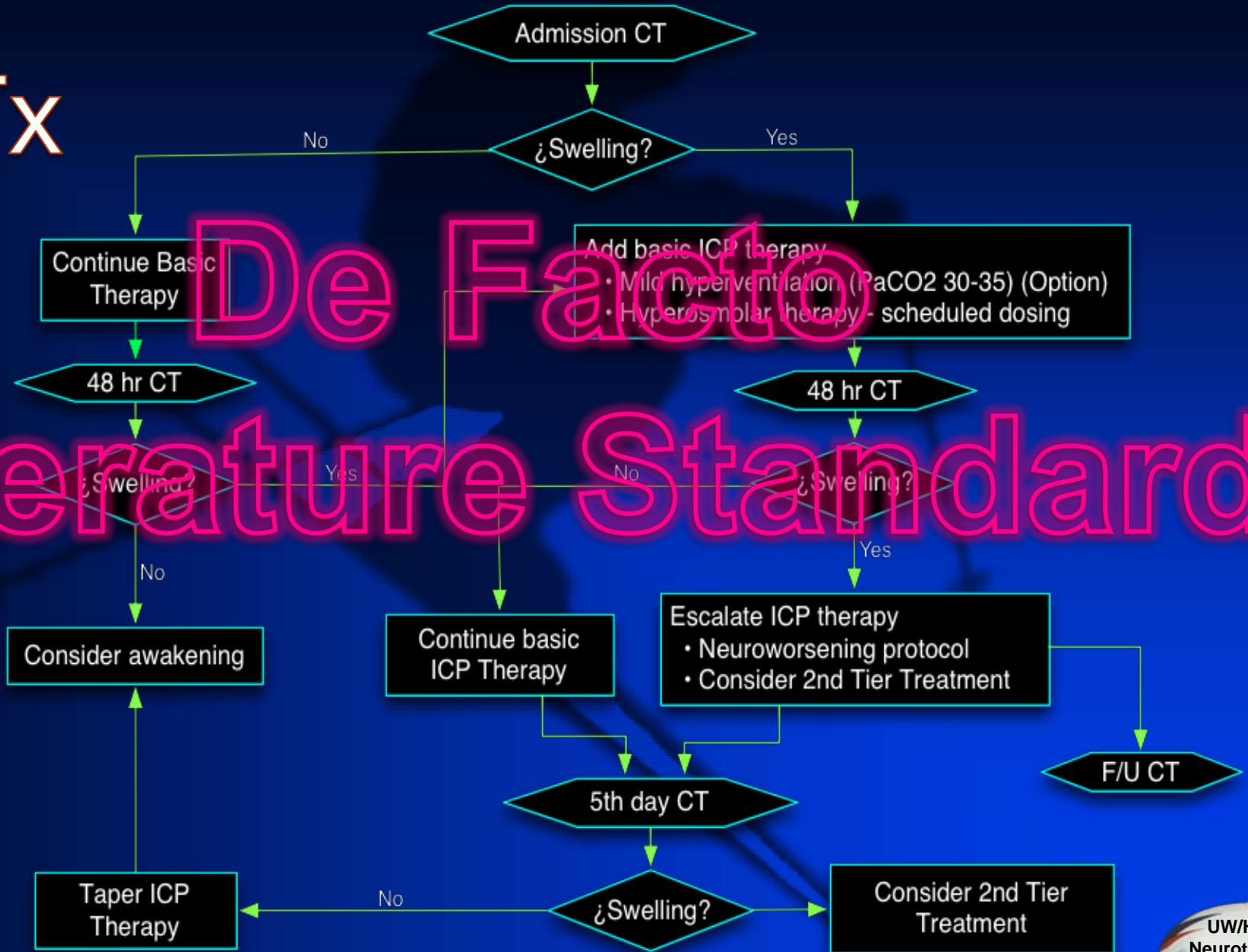
eyya Dikmen,³ Nancy Temkin,³ Gustavo Petroni,²
er,³ Mariana Cherner,⁴ Kelley Chaddock,³ Terence Hendrix,⁴
ita,⁵ Juanita M. Celix,³ and Randall Chesnut³

CHICAGO, ILLINOIS OCTOBER 6-10, 2012

UW/HMC
Neurotrauma
Research Group

ICE Tx

De Facto Literature Standard



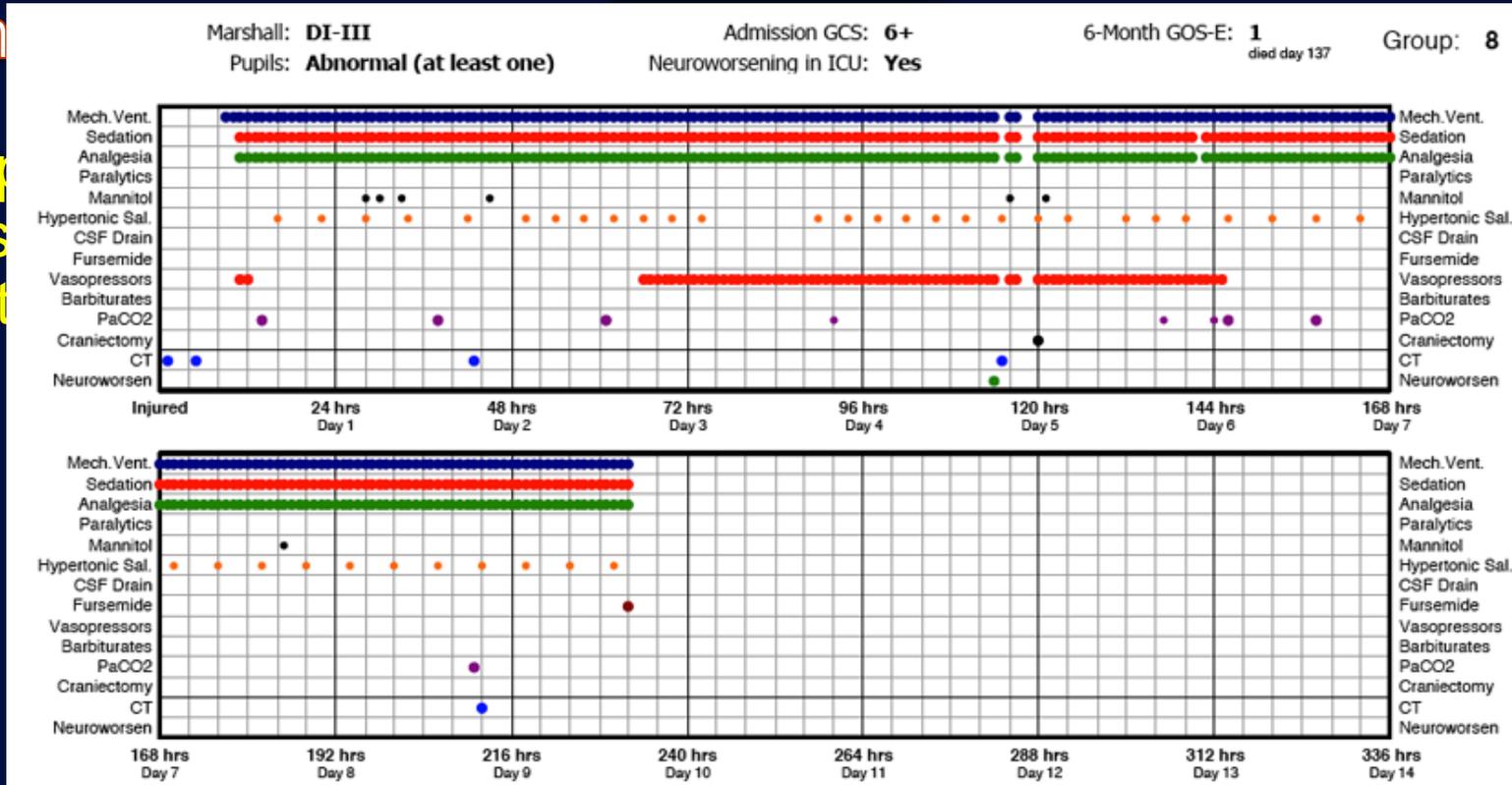
A world map is shown in the background, rendered in a light blue color against a dark blue background. The map is centered and shows the outlines of the continents.

>95% of sTBI is Tx'd
without ICP monitoring

The UW Latin American TBI Project

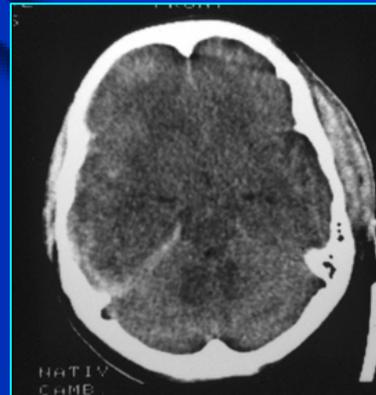
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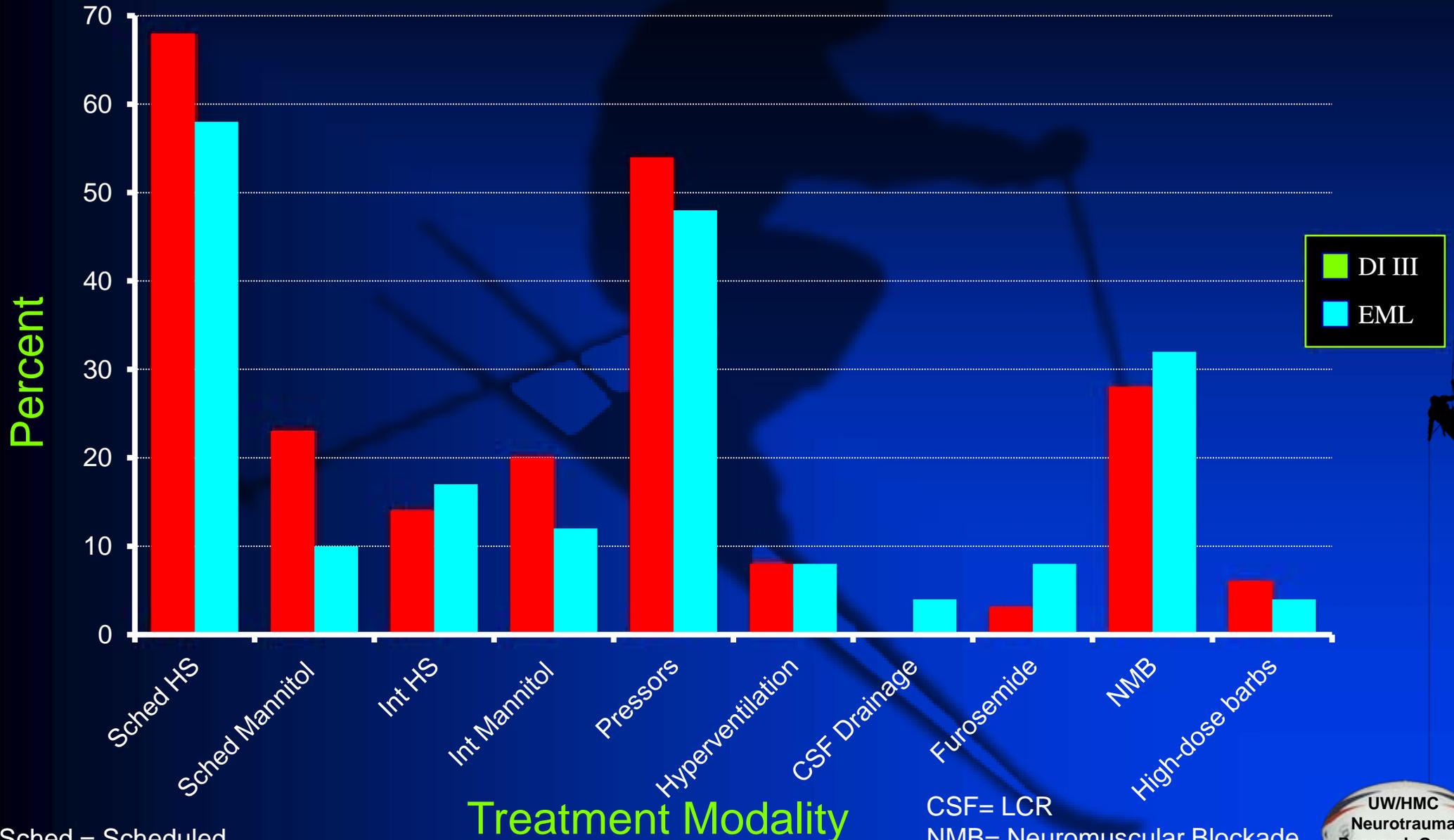


02

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Use of Treatment Modalities



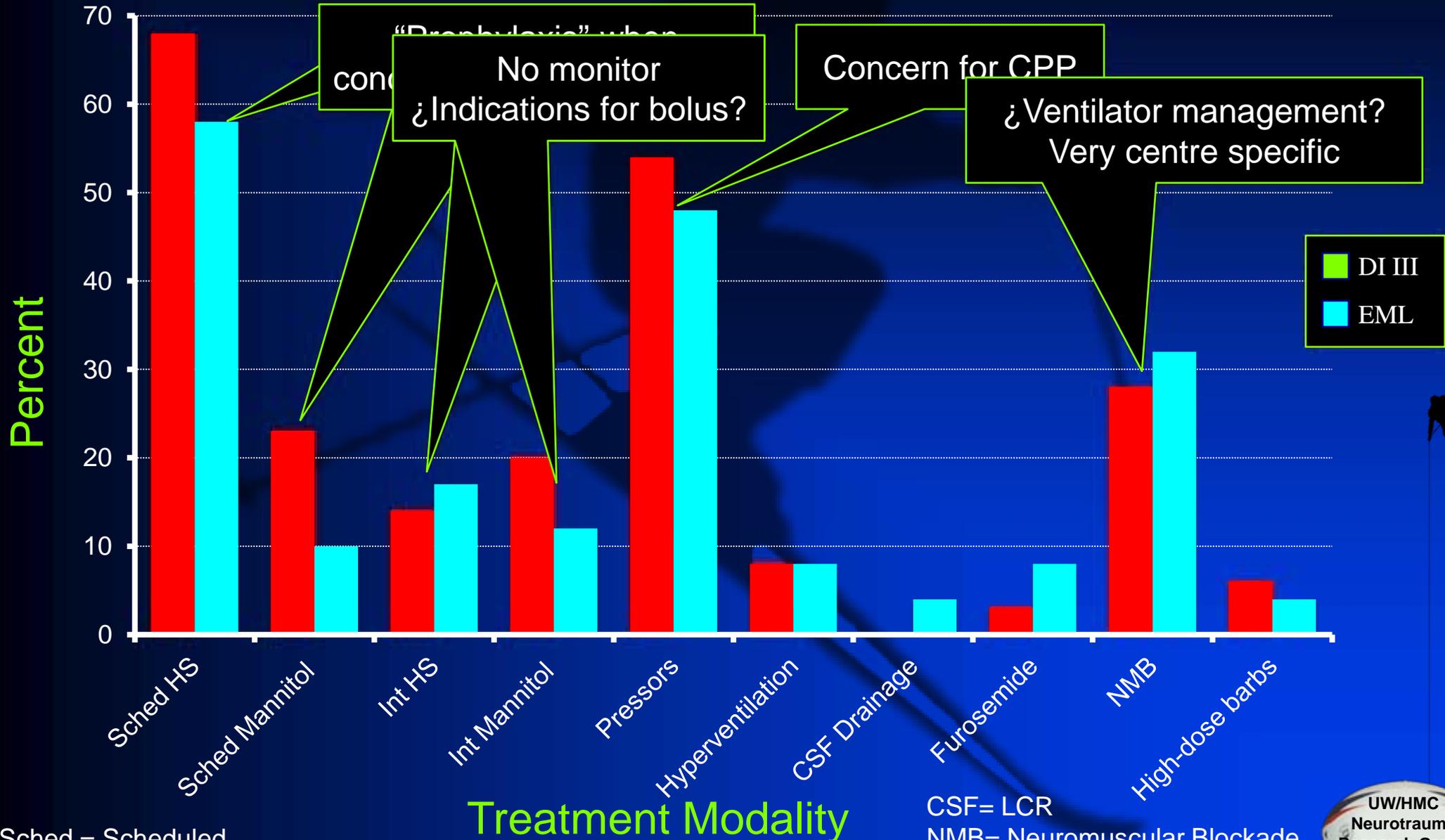
Sched = Scheduled
Int = Intermittent

Treatment Modality

CSF= LCR
NMB= Neuromuscular Blockade
Barbs = Barbiturates



Use of Treatment Modalities



Sched = Scheduled
Int = Intermittent

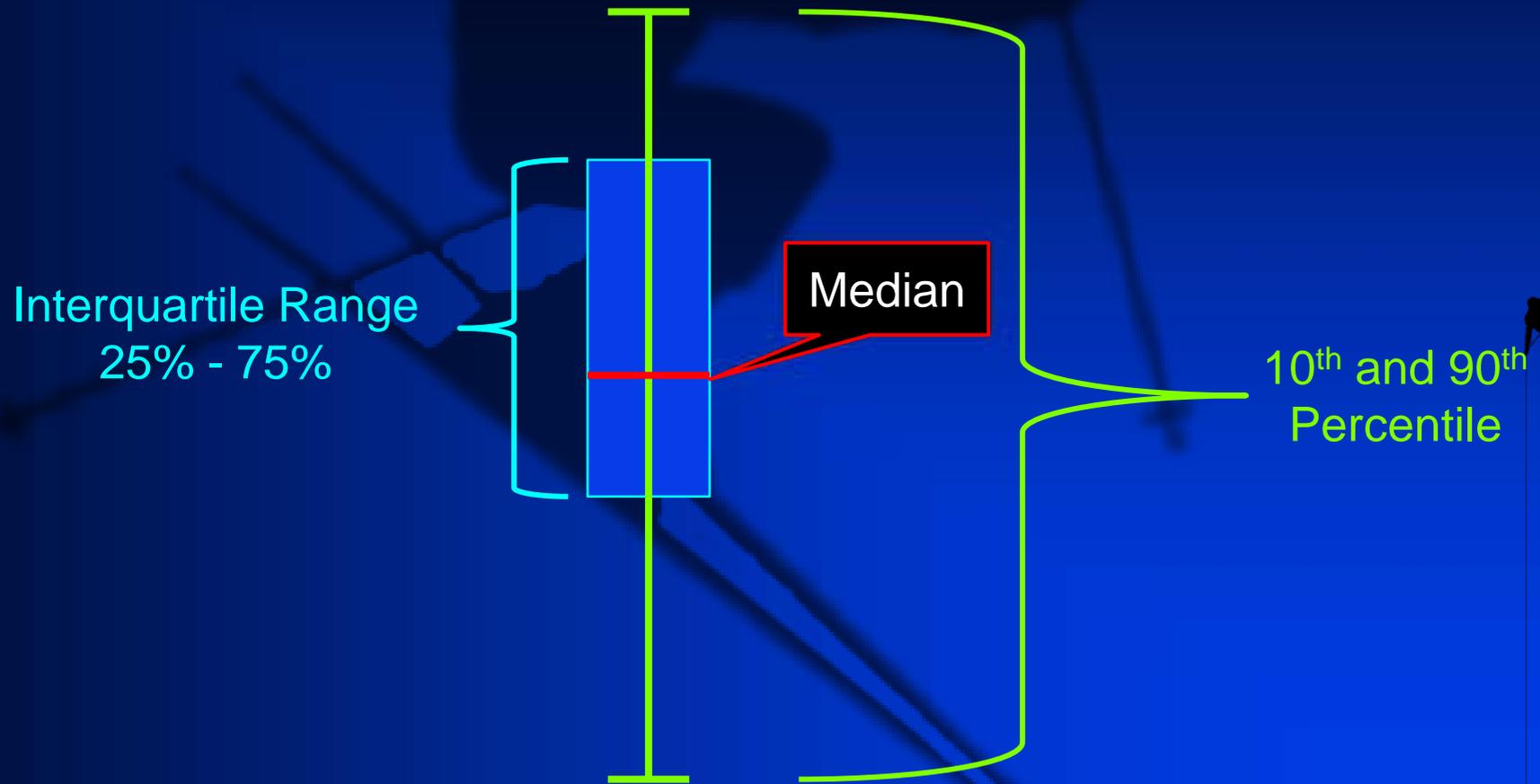
Treatment Modality

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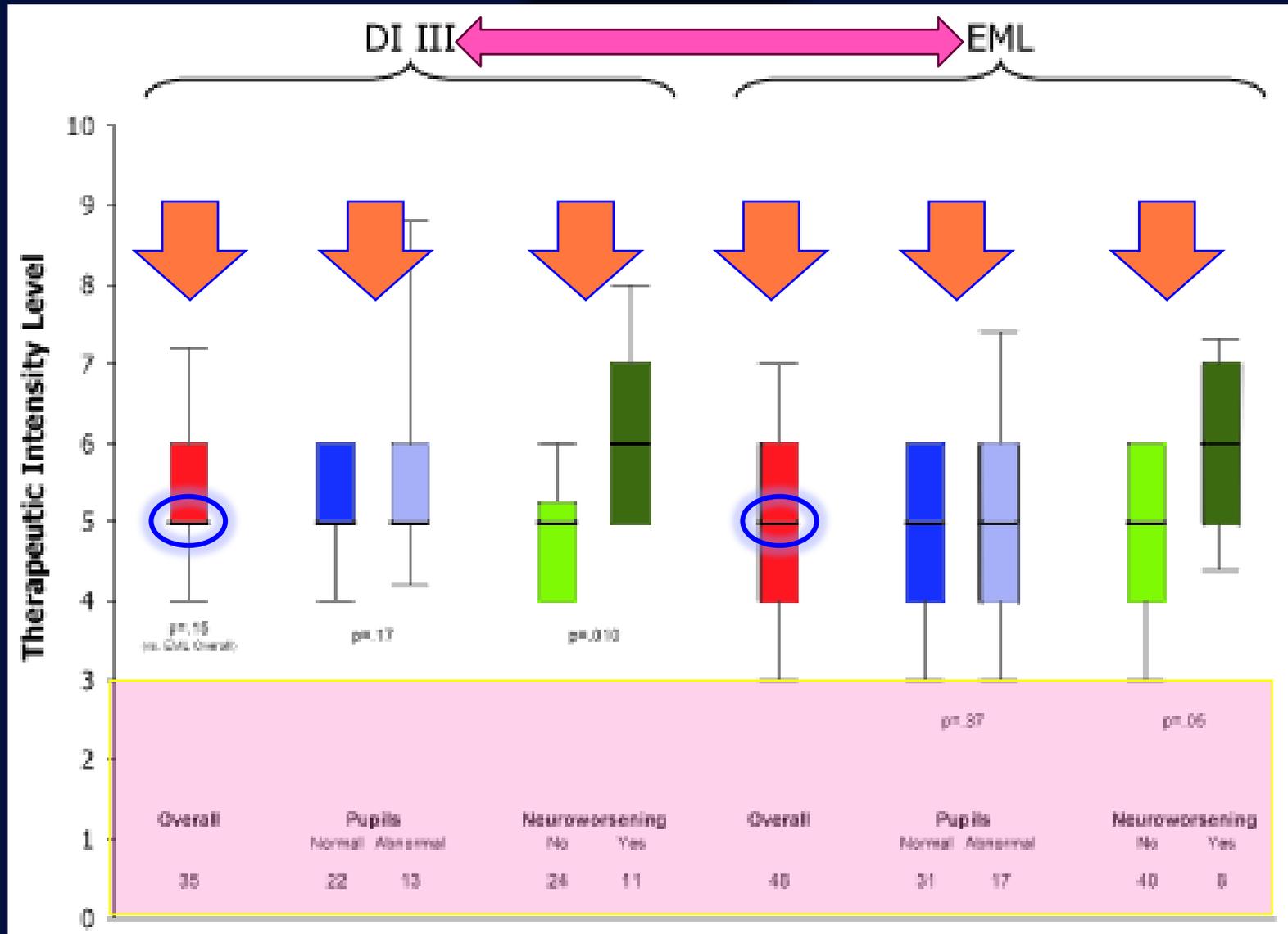


Box Whisker Plots

Technique for showing distribution of observations



Use of ICP Treatments without Monitoring

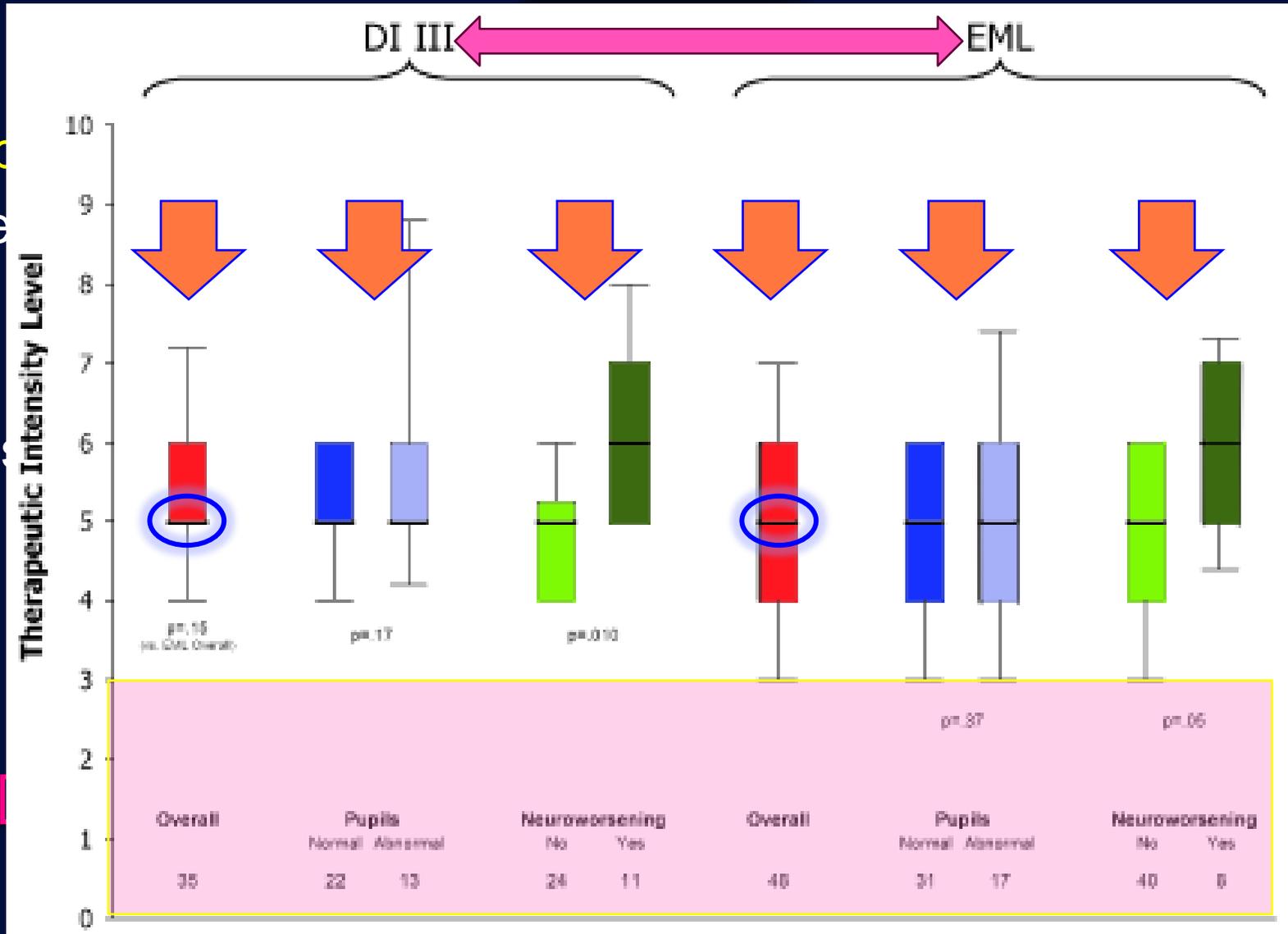


Use of ICP Treatments without Monitoring

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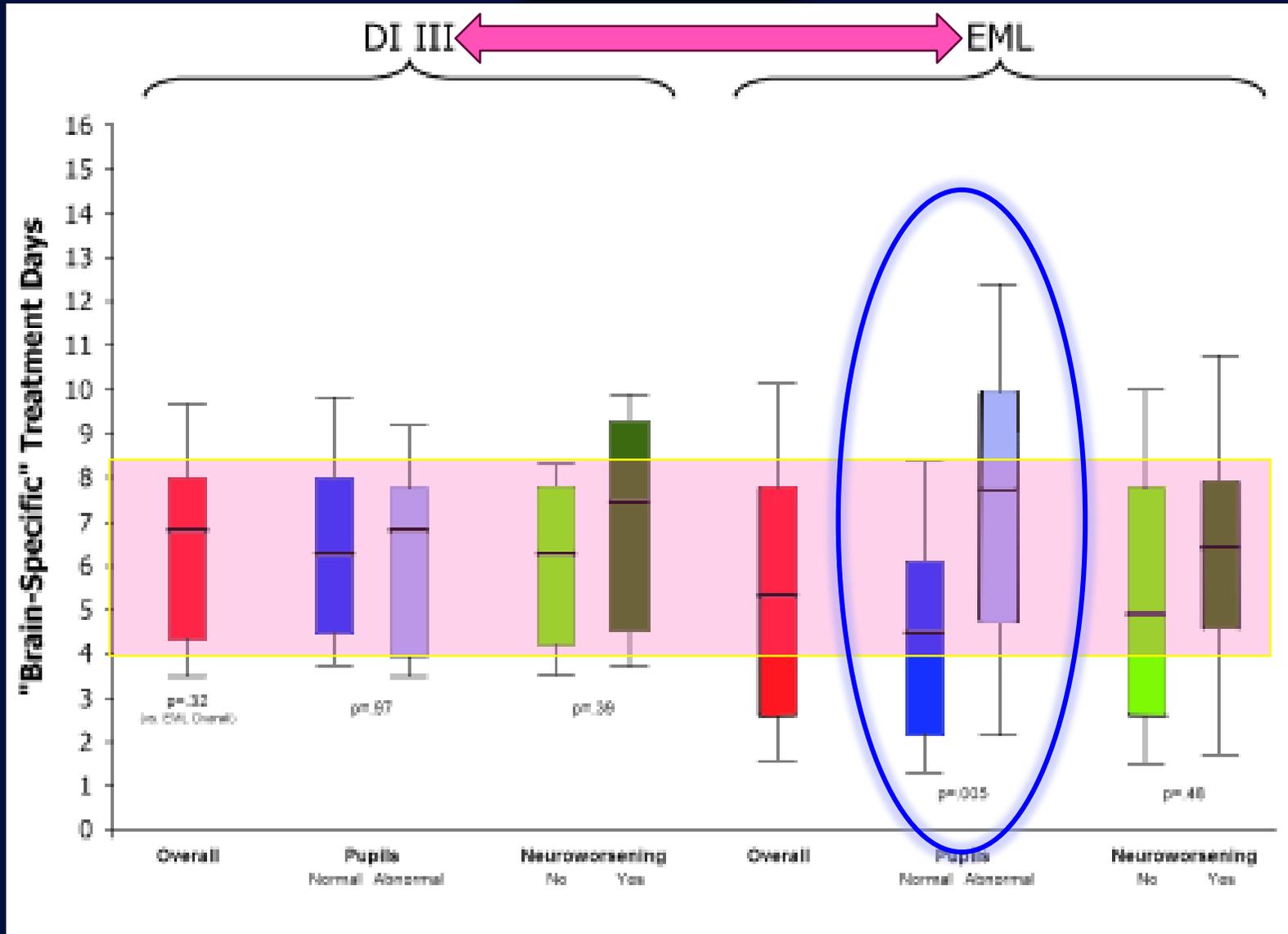


EML

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ICP Treatment Days Without Monitoring

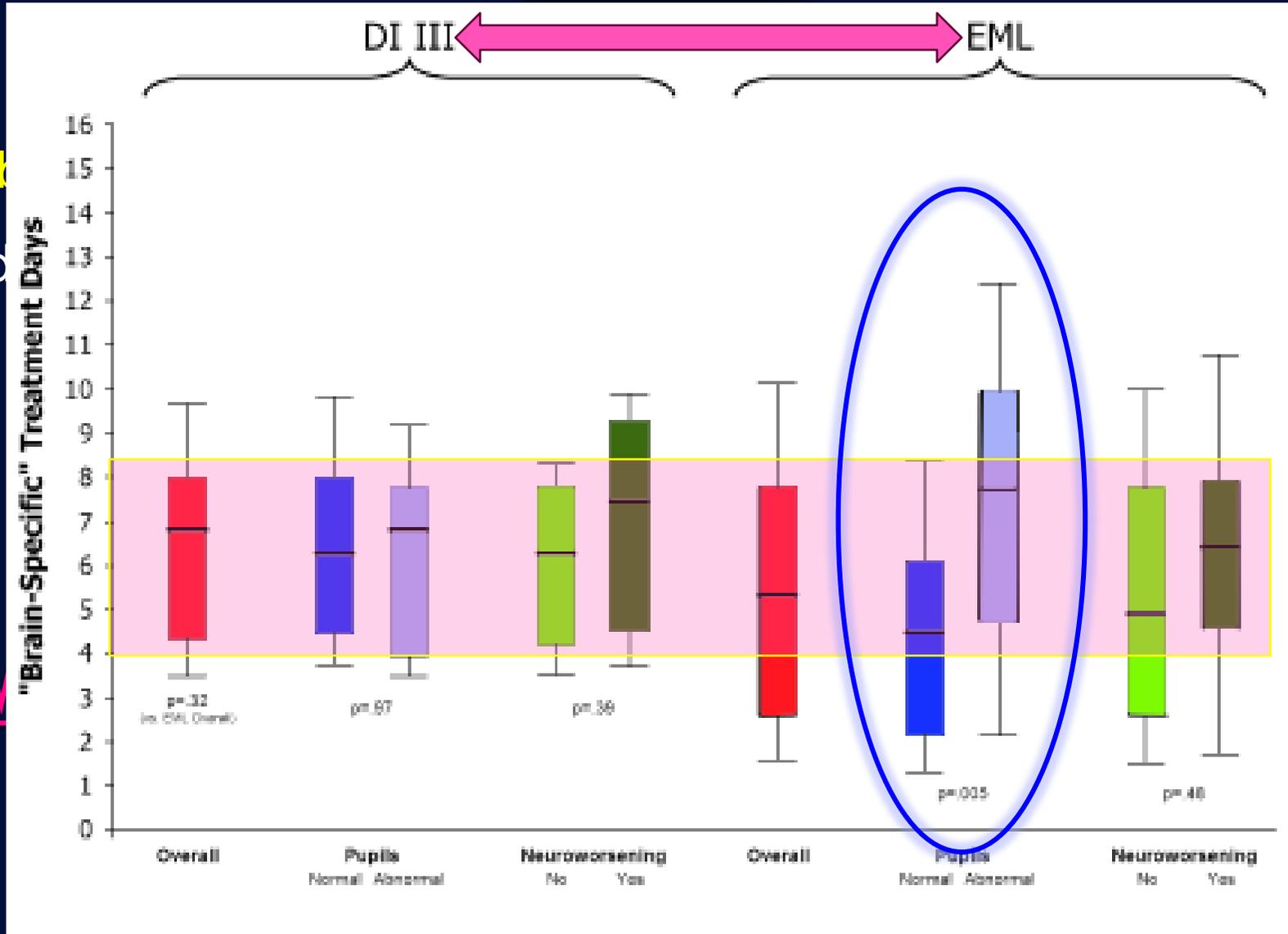


ICP Treatment Days Without Monitoring

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unclear

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Prior Exposure Group

No Prior Exposure Group

Ad Hoc RCT Protocol

Data Collection

No Protocol

Phase 1
18 mos.

Develop Guidelines, Protocol

6 mos.

**IRB Approvals
Introduce Guidelines, Protocol**

ca. 6 mos.

Phase 2
18 mos.

Data Collection

Guidelines Protocol

Guidelines Protocol

Prior Exposure Group

No Prior Exposure Group

Ad Hoc RCT Protocol

No Protocol

Data Collection

Influence of protocols in general

Phase 1
18 mos.

Develop Clinical Trials, Protocol

6 mos.

Optimisation of Treatment

ca. 6 mos.

Introduce Clinical Trials, Protocol

Phase 2
18 mos.

Data Collection

Guidelines Protocol

Guidelines Protocol

Prior Exposure
Group

No Prior
Exposure
Group

Ad Hoc
RCT Protocol

Ad Hoc
Protocol

Phase 1
18 mos.

Data Collection



Develop Guidelines, Protocol

6 mos.

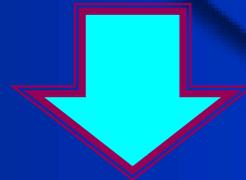
IRB Approvals

Introduce Guidelines, Protocol

6 mos.

Phase 2
18 mos.

Data Collection



Guidelines
Protocol

Guidelines
Protocol

El Futuro

Long Term

Develop an optimised protocol for Tx of sTBI without ICP monitoring

¿¿¿Refine the management of monitored sTBI patients???

Short Term

Continue the development of research capacity in Latin America

- Further involvement of current (“experienced”) centres
- Bringing in new centres

Assist current centres to use their data to better their realities

- Medical
- Administrative
- Political

Promote academic development of interested investigators

- Scientific writing workshop for publication in English and Spanish/Portuguese journals

El Futuro

Long Term



*Centro de Informática e
Investigación Clínica*

Assist current centres to use their data to better their realities

- Medical
- Administrative
- Political

Promote academic development of interested investigators

- Scientific writing workshop for publication in English and Spanish/Portuguese journals

Funding International Research



Funding International Research



United States

University of Washington

Harborview Medical Center

Randall Ch...
Nancy Te...
Sureyya Dikn...
James Pridge...
Jason Barber...
Joan Machan...
Kelley Chadd...
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Site Coord...
Follow-up

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Uruguay: Dra. Corina Puppo
Columbia: Dr. Ricardo Romero Figueroa

Hospital de Emergencias, Rosario

Carlos Rondina MD
Gustavo Petroni MD
Silvia Lujan MD

- Monitors & cateters
- Annual financial donations

Financial donations

• Richard Adler
• Mike Nelson

Observation Site Investigators

Brazil: Dr. Antonio Luis Eiras Falcao
Uruguay: Dra. Corina Puppo
Columbia: Dr. Ricardo Romero Figueroa

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Study Coordinator -
Follow-up -
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Lic. Maria...

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Country coordinator, La Paz, Bolivia
Dr. Freddy Sandi Lora

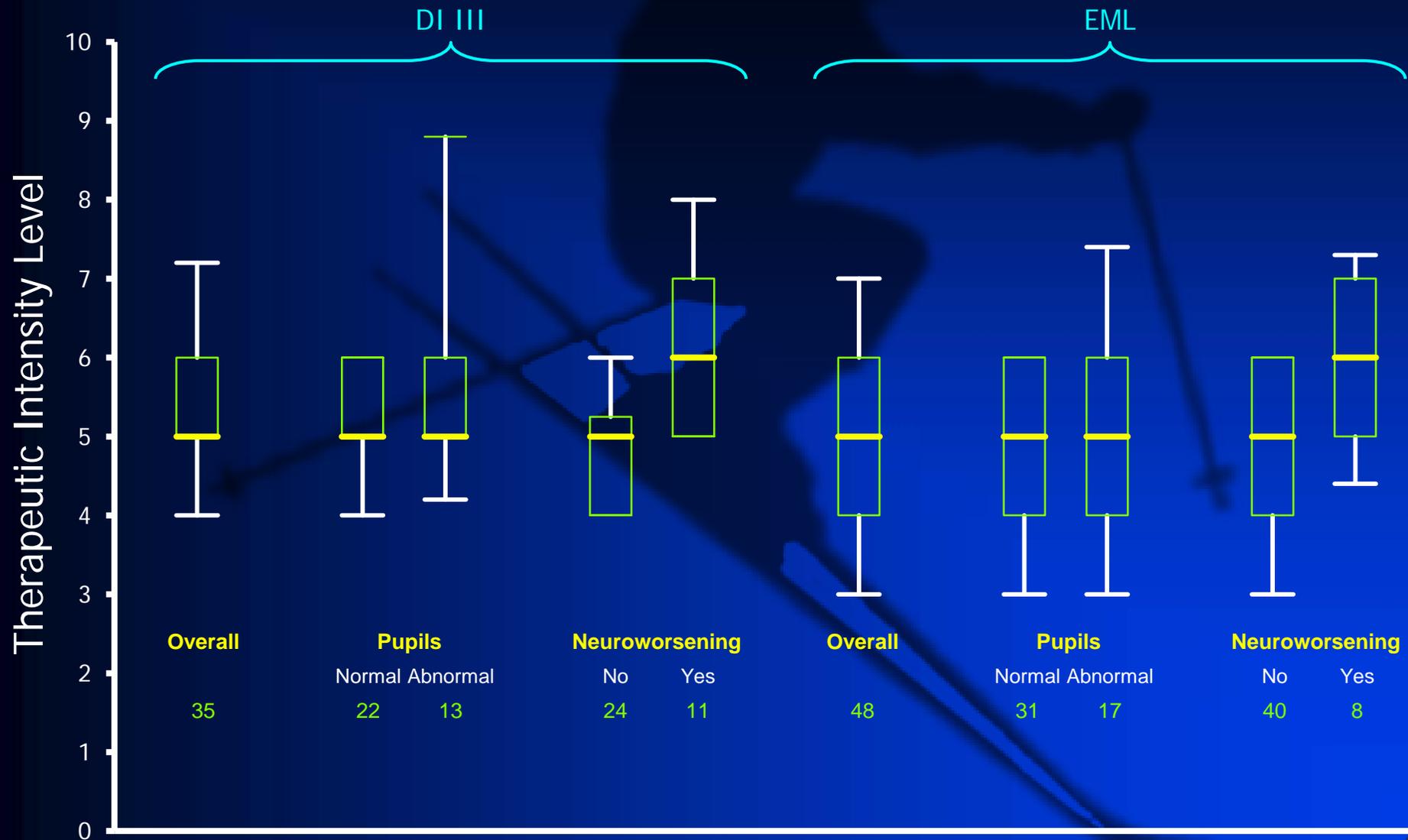
Thank You!

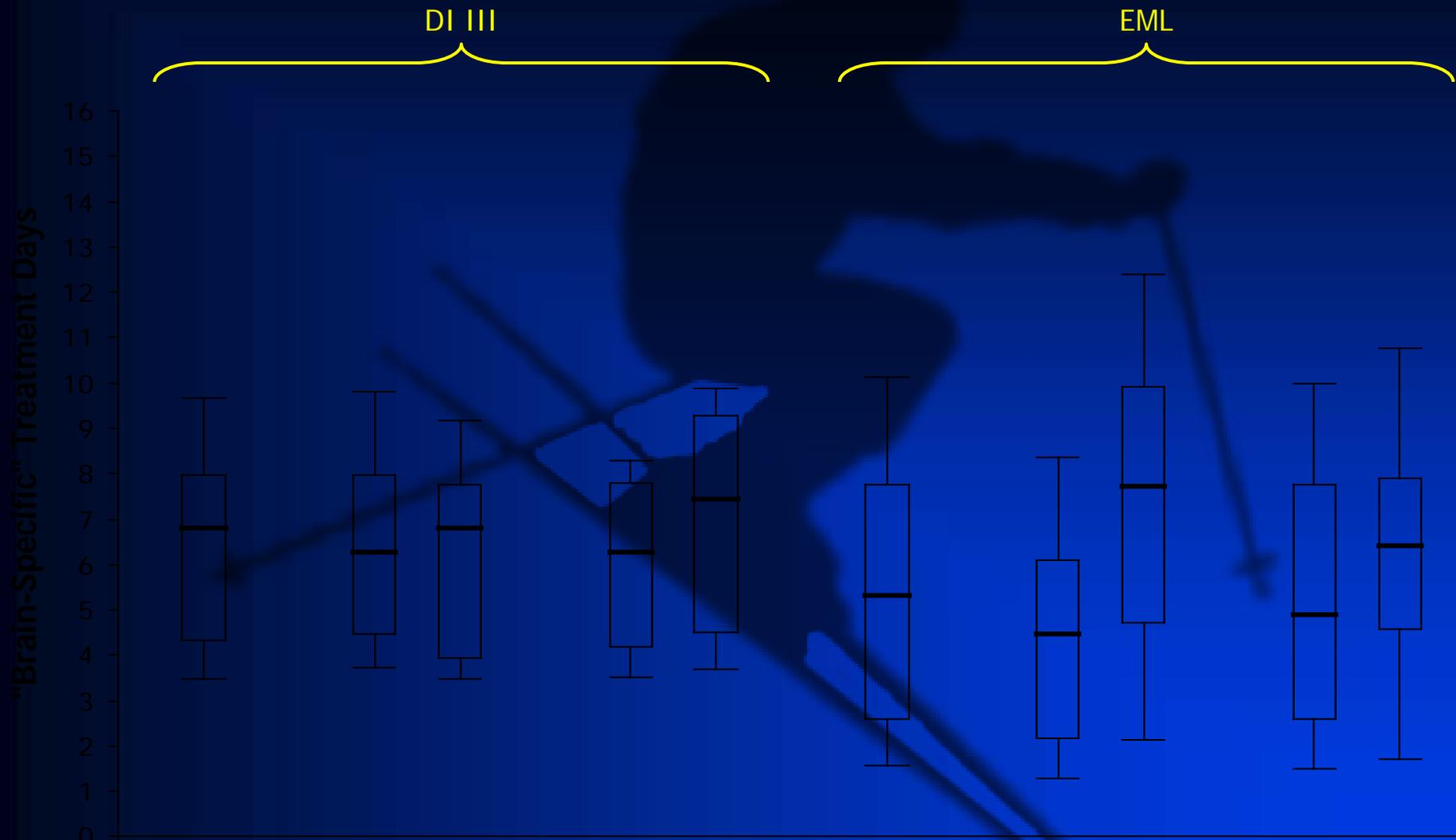
¡Muchas Gracias!

¡Obrigado!

Ecuador

Bolivia





Legend	Overall	Pupils		Neuroworsening		Overall	Pupils		Neuroworsening	
		Normal	Abnormal	No	Yes		Normal	Abnormal	No	Yes
	Count	Count	Count	Count	Count	Count	Count	Count	Count	Count
Blue	35	22	13	24	11	48	31	17	40	8

