

# Emergent Surgical Treatment of Severely Injured Hemorrhagic Shock Patients Enrolled in the EU and US DCLHb Clinical Trials

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## DCLHb Study Investigators

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### Introduction: Clinical Issues

- Traumatic Hemorrhagic Shock (THS) associated with high mortality
- Interventions within Golden Hour
- Emergent Surgery
  - Immediately after ED stabilization
  - Proven to reduce mortality
  - Rationale for Level 1 Trauma Centers

### Methods: EU & US DCLHb Trial Designs

- DCLHb: human hemoglobin solution
- Randomized, controlled, single-blinded
- Trauma Centers: 18 US & 32 EU sites
- Pts: severe traumatic hemorrhagic shock
- Standard Rx, with DCLHb add-on in ED
  - Fluid limit = 1L before DCLHb in EU trial
  - DCLHb infused prehospital in EU trial

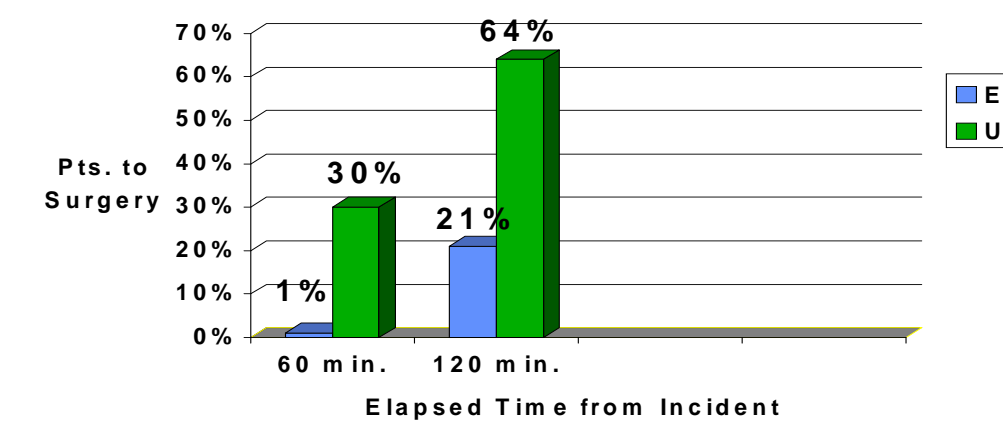
### Results: Demographics (All Pts.)

Characteristic	EU	US	p
Age (Mean)	35 y/o	39 y/o	.17
Gender (Male)	68%	79%	.11
MOI (Blunt)	70%	58%	.05

MVA: 83/138 = 60% of Blunt MOI pts.

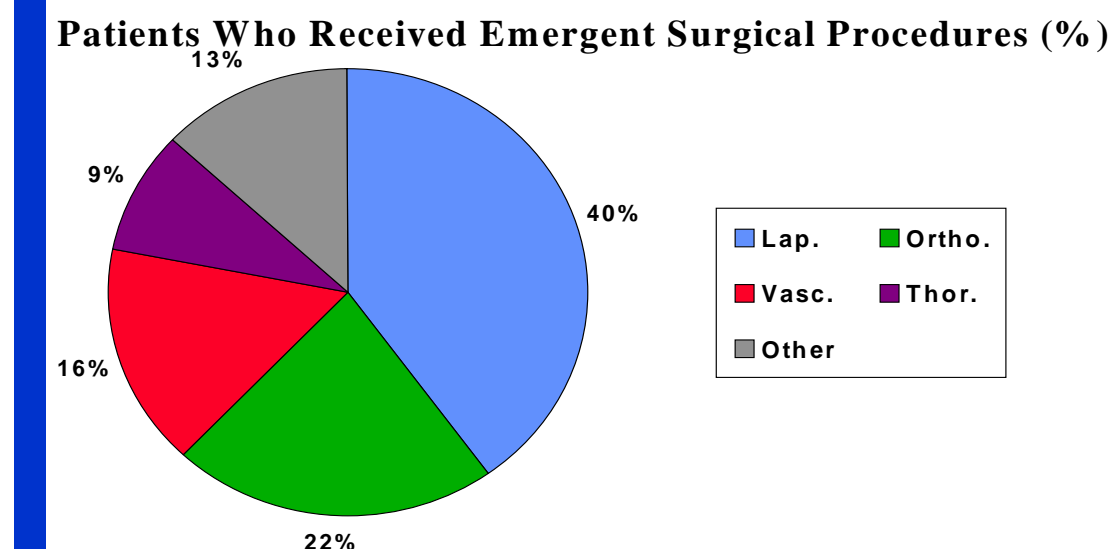
- Similar pt. demographics in EU & US

### Results: Time to Surgery vs. Setting



- >% US pts. ⇒ OR in 60 min. (30% vs. 1%, p < .001)
- >% US pts. ⇒ OR in 120 min. (64% vs. 21%, p < .001)

### Results: Surgical Procedures



### Conclusions: Surgical Patients

- Most pts. required emergent surgery
- Blunt & Pen. MOI nearly equal
- One-third received multiple procedures
- Similar demographics in EU & US
  - Emergent surgery pts. %
  - Age
  - MOI
  - 48-hour mortality %

### Introduction: Study Questions

- How many receive emergent surgery?
- What are the most common surgeries?
- How many in surgery 1 hr. after injury?
- Do the data differ by MOI or continent?
- Is there any correlation with mortality?

### Methods: Secondary Analysis

- MOI recorded as Blunt or Penetrating
- Golden Hour = 60 min. from est. injury time
- Surgeries immediately after ED disposition
- Reported multiple surgeries per given pt.
- Mortality recorded at 48-hours
- Statistical analysis: SPSS v.10, EpiInfo
  - Descriptive statistics
  - Student's t-test, odds ratios

### Results: Emergent Surgical Patients

Char.	EU	US	Overall
n (%)	76 (64%)	70 (71%)	146 (67%)
Blunt MOI	45 (59%)	37 (53%)	82 (56%)
Age	35.2 ± 14.5	36.0 ± 17.6	35.6 ± 16.0
Age ≥ 65	3 (4%)	6 (9%)	9 (6%)
Mortality	21 (28%)	18 (26%)	39 (27%)

MVA: 52/82 = 63% Blunt MOI pts.

- Similar pt. demographics in EU & US

### Results: MOI & Time Course

Time (min.)	Blunt	Penetrating	p
Inc. ⇒ ED	83.0 ± 41.2	58.8 ± 37.8	<.001
ED ⇒ OR	146.4 ± 174.0	82.2 ± 155.9	.02
Inc. ⇒ OR	234.2 ± 188.3	156.7 ± 189.0	.01

Mean Inc. ⇒ ED, MVA vs. non-MVA: 82.2 ± 42.1 vs. 68.4 ± 40.5, p = .02

### Results: Surgery vs. MOI (n = 146)

Surgical Procedure	Blunt (n = 82)	Pen. (n = 64)	OR	p
Laparotomy	48 (59%)	26 (41%)	2.1	.05
Splenectomy	27 (33%)	2 (3%)	15.2	<.001
Orthopedic	26 (32%)	10 (16%)	2.5	.04
Vascular	9 (11%)	20 (31%)	3.7	.005
Thoracotomy	8 (10%)	9 (14%)	3.5	.33

Proc. ≥ 2 sys. by MOI: 34% vs. 37%, p = .80

### Conclusions: Time Course

- Minority of pts. entered OR 60 min. after injury (Golden Hour)
  - Pts. % more than tripled after 120 min.
- Factors affecting Golden Hour
  - EU setting
    - Longer mean total EMS & ED to OR times
  - Blunt MOI
    - Majority were MVA
    - Likely extrication ⇒ longer EMS time

### Objectives: Clinical Impact

- Reports frequency and time course of surgery among severe THS pts.
- Describes surgeries performed
- Examines Blunt vs. Penetrating MOI, European (EU) vs. US settings
- Mortality vs. MOI and surgical procedure
- Suggestions to optimize design of future hemorrhagic shock trials, resuscitation

### Results: DCLHb Trials' Outcomes

- EU Trial: Jul. '97 – May '98
  - Enrolled & infused 119 pts.
- US Trial: Feb. '97 – Jan. '98
  - Enrolled & infused 98 pts.
  - Early study termination
  - DCLHb: Higher 28-day mortality
  - No clear explanation of imbalance

### Results: Time Course & Setting

Time (min.)	EU	US	p
Inc. ⇒ ED	88 ± 35	58 ± 43	<.001
ED ⇒ OR	178 ± 208	54 ± 68	<.001
Inc. ⇒ OR	277 ± 224	113 ± 87	<.001

- US 34% faster than EU from Incident to ED, and 70% faster from ED to OR.

### Results: Surgical Procedures

Procedure (n = 182)	Pts.	Percentage
Laparotomy	74	41%
Splenectomy	29	39% of lap.
Hepatic Repair	18	24% of lap.
Other Viscus Repair	23	31% of lap.
Orthopedic	36	20%
Vascular	29	17%

Surgery ≥ 2 organ systems: 52/ 146 (36%) pts.

### Results: Surgery & 48-hour Mortality

Procedure	Mortality	Blunt	Pen.	OR	p
Laparotomy	26 (35%)	20 (41%)	6 (24%)	2.2	.24
Orthopedic	3 (8%)	2 (8%)	1 (10%)	0.8	1.0
Vascular	6 (21%)	3 (33%)	3 (15%)	2.8	.34
Thoracotomy	9 (53%)	6 (75%)	3 (33%)	6.0	.15
Overall	39 (27%)	29 (35%)	10 (16%)	3.0	.01

• Increased 48-hr. mortality among blunt MOI pts., (35% vs. 16%, OR = 3.0, p = .01).

• Increased mortality among all thoracotomy pts., (59% vs. 24%, OR = 4.5, p = .007).

### Conclusions: MOI, Procedures, & Mortality

- Procedures associated w/ Blunt MOI:
  - Laparotomy (esp. splenectomy)
  - Orthopedic (all)
  - No association with mortality by procedure
  - Increased overall 48-hr. mortality
- Procedures associated w/ Penetrating MOI:
  - Vascular
  - No association with mortality by procedure
- Thoracotomy frequency did not differ by MOI
  - Trend: increased 48-hr. mortality w/ Blunt MOI
  - Increased overall 48-hr. mortality





