Witten/Herdecke

Registerergebnisse am Beispiel der Schwerverletztenversorgung

TraumaRegister DGU®

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Operativen Medizin (IFOM)

Beteiligte Kliniken

bis 2014

Gesamt:	**674**
aktiv in 2014	**617**
inaktiv	57

D:	637 (582)
A:	18 (18)
NL:	4 (4)
B:	4 (4)
CH:	3 (3)
LUX:	3 (3)
SI:	5 (1)
FIN:	1 (1)
VAE:	1 (1)
China:	1 (0)

VAE 1
China 1

Map annotations: 1 (Finland), 4, 4, 637, 3, 18, 3, 5

Chart legend:
- inaktiv
- aktiv

Bar chart values (aktiv):
Year	Value
1993	7
1994	8
1995	13
1996	15
1997	18
1998	25
1999	39
2000	51
2001	73
2002	64
2003	64
2004	65
2005	72
2006	92
2007	106
2008	122
2009	218
2010	367
2011	509
2012	572
2013	614
2014	617
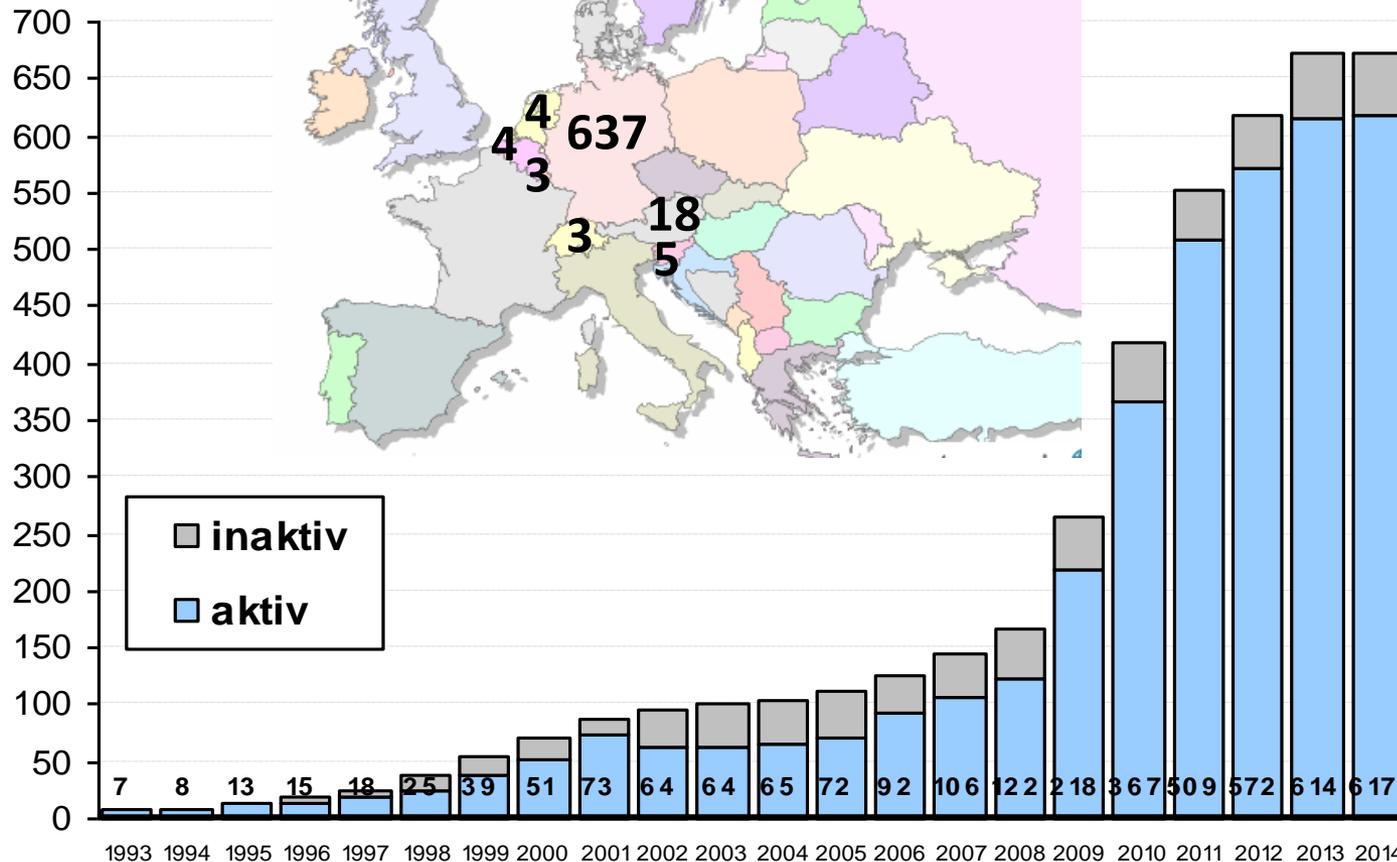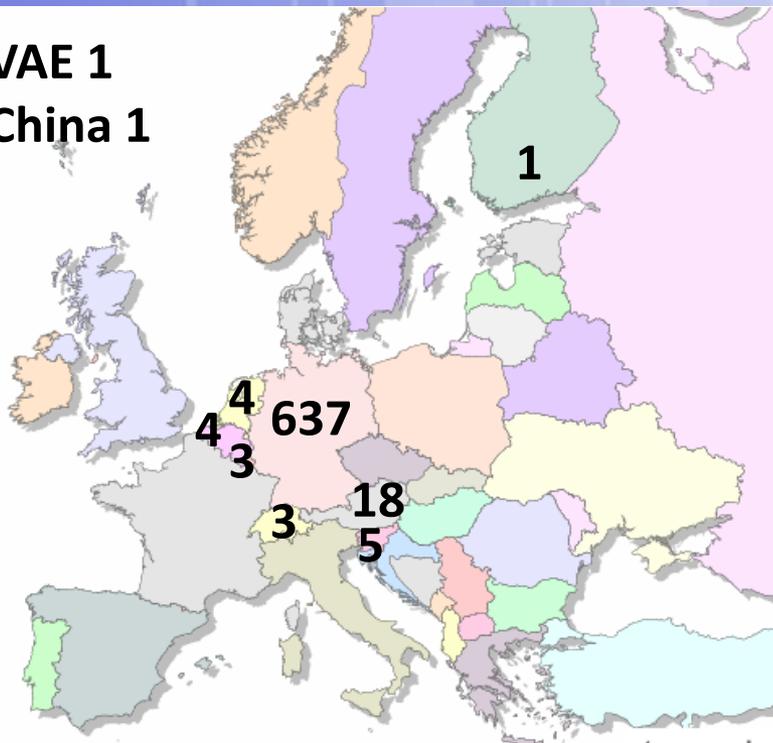
906 Kliniken mit Unfallchirurgie /
Orthopädie; 694 auditiert   **2015**   52 zertifizierte TraumaNezwerke
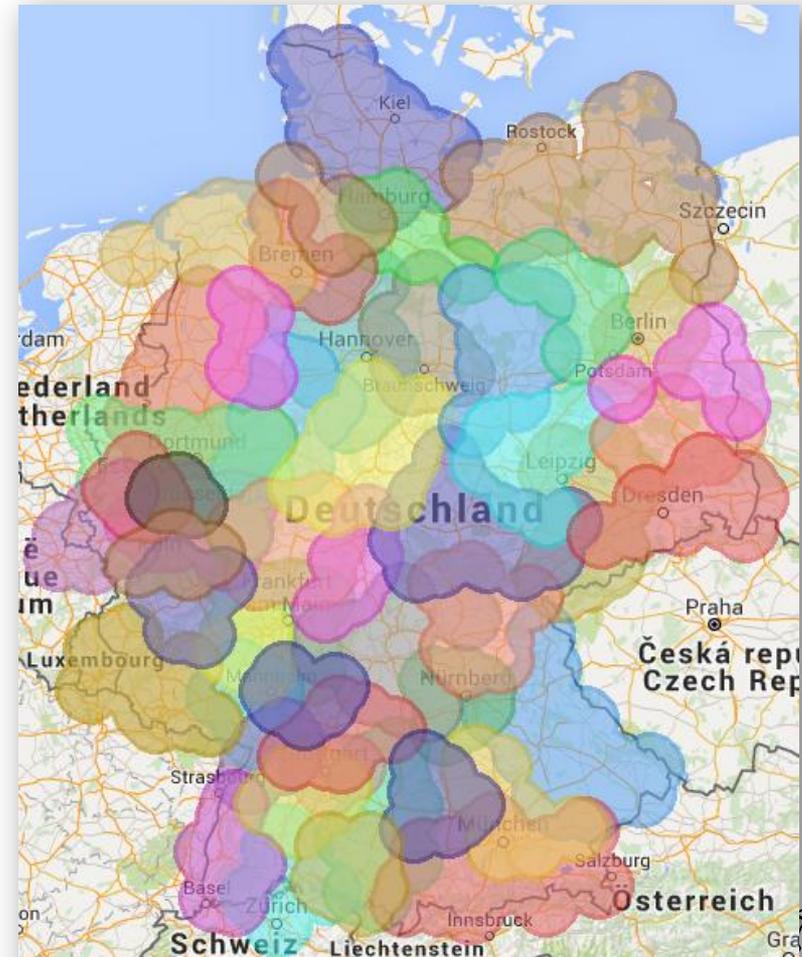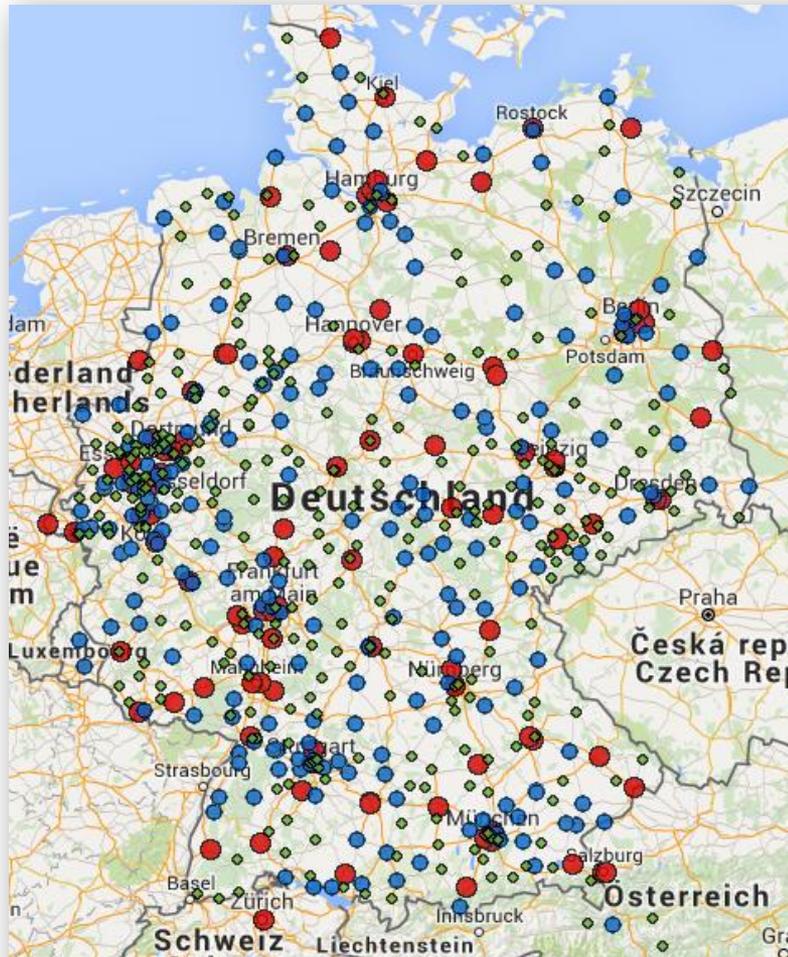
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Patienten im TraumaRegister DGU®
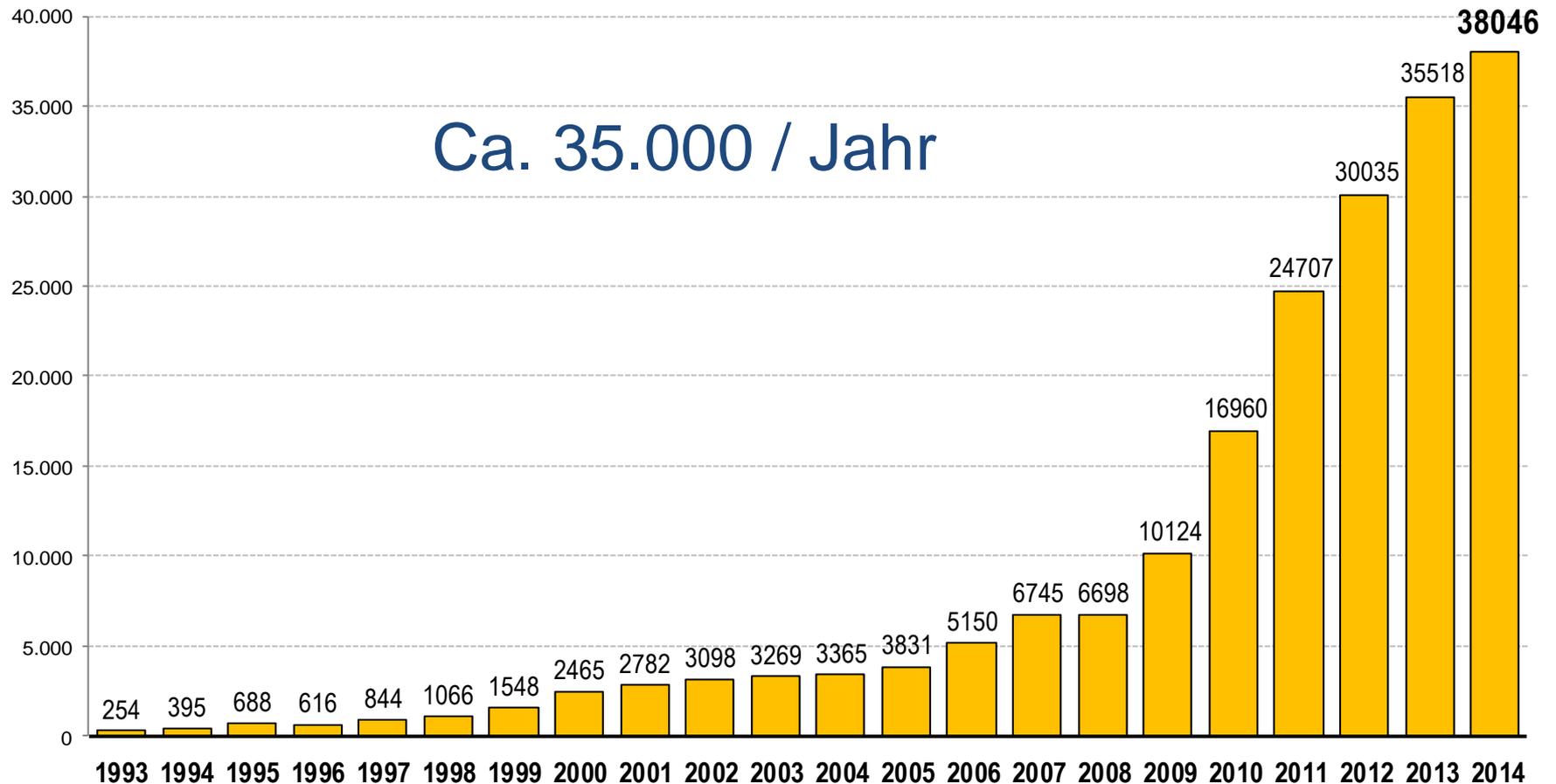
Ca. 35.000 / Jahr

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Ziele

Durchführung einer anonymen externen vergleichenden **Qualitätssicherung**
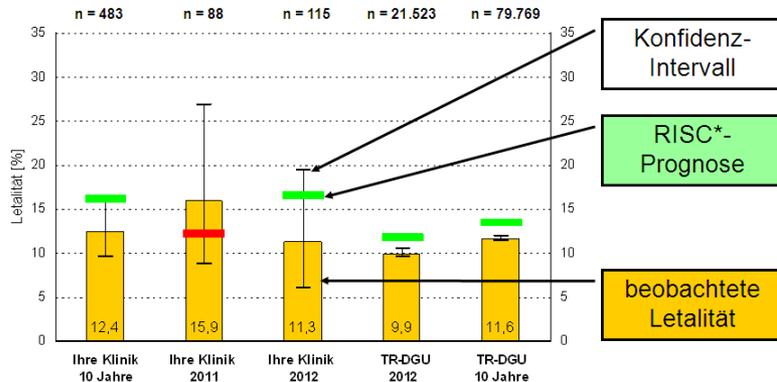
- Rückmeldung; Qualitätsberichte

- Indikatoren

Wissenschaftliche Auswertungen zur Versorgung Schwerverletzter

- Versorgungsrealität

- Epidemiologie; Verletzungen

- Outcome
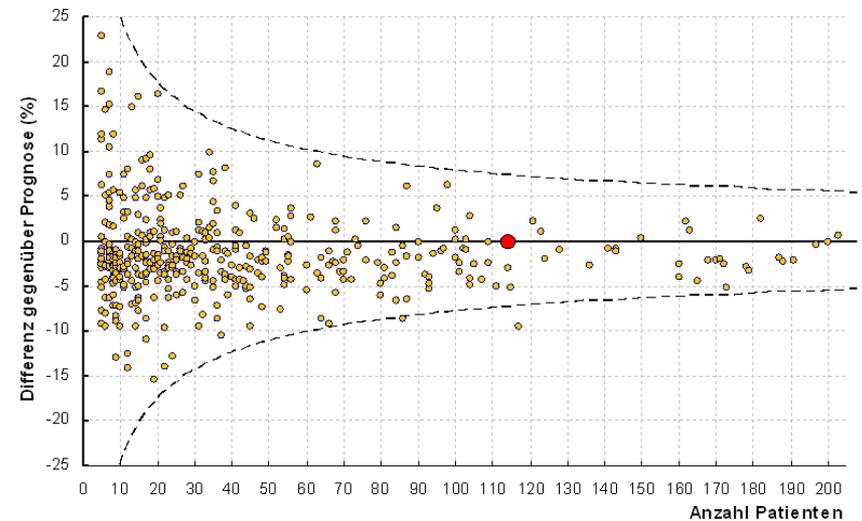
- Ökonomie

- Evaluation von Maßnahmen

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TraumaRegister DGU® - Jahresbericht

n = 483   n = 88   n = 115   n = 21.523   n = 79.769

Letalität [%]

- Konfidenz-Intervall
- RISC*-Prognose
- beobachtete Letalität

	12,4	15,9	11,3	9,9	11,6
	Ihre Klinik 10 Jahre	Ihre Klinik 2011	Ihre Klinik 2012	TR-DGU 2012	TR-DGU 10 Jahre

Differenz gegenüber Prognose (%) — Anzahl Patienten

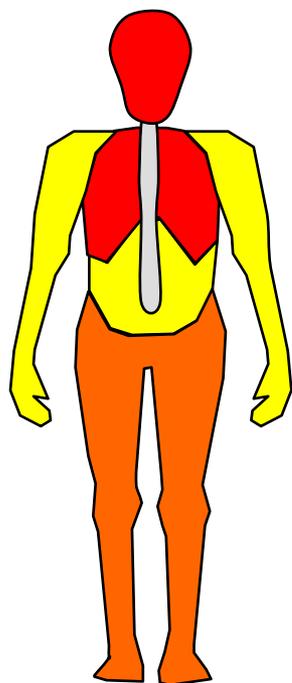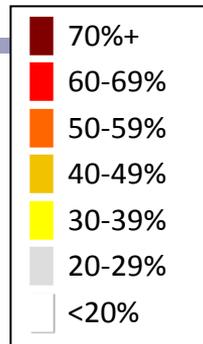| Kriterien	Ihre Klinik				TR-DGU	
	10 Jahre	2010	2011	2012	2012	10 Jahre
Primär versorgte Patienten	n=97.101	n=15.283	n=22.082	n=26.377	n=26.377	n=97.101
1. Dauer der präklinischen Zeit zwischen Unfall und Klinikaufnahme bei Schwerverletzten mit ISS ≥ 16 [∅ min ± SD]	71 ± 50 n=45.466	72 ± 53 n=6.771	71 ± 54 n=9.463	70 ± 52 n=10.414	70 ± 52 n=10.414	71 ± 50 n=45.466
2. Intubationsrate bei bewusstlosen Patienten (GCS ≤ 8) [%, n / gesamt]	88% 16.431/18.618	88% 2.474/2.814	86% 3.035/3.548	84% 3.394/4.045	84% 3.394 / 4.045	88% 16.431 / 18.618

Injury Severity Score (ISS)

- Ihre Klinik
- Median (50%) der Klinikwerte
- 10%-90% der Kliniken

	Ihre Klinik 2012		TR-DGU 2012		TR-DGU 10	
Anzahl Patienten	253		28.805		108.986	

(S) Stammdaten / Unfall

	%	n	%	n	%	n
Primärversorgung / Verlegung						
primär versorgt	92,1	233	91,6	26.377	89,1	97.101
davon früh (innerh. 48 h) weiterverlegt	0,4	1	6,6	1.887	5,3	5.760
zuverlegt innerhalb 24 h nach Unfall	7,1	18	7,5	2.161	9,7	10.558
zuverlegt später als 24 h	0,8	2	0,9	267	1,2	1.332
Patientendaten						
Alter in Jahren (MW ± SD, n)	46,3 ± 22,2	253	47,6 ± 22,2	28.750	45,9 ± 21,9	108.479
Anteil **Kinder** unter 16 J. (%, n)	7,1	18	4,9	1.418	5,2	5.633
Geschlecht männlich (%, n)	78,3	198	70,2	20.217	71,0	77.365
Pat. mit **ASA 3-4** vor Trauma * (%, n)	12,5	31	13,7	3.410	13,1	8.883
Unfallmechanismus	%	n	%	n	%	n
stumpf	93,6	235	94,9	25.741	95,1	98.669
penetrierend	6,4	16	5,1	1.391	4,9	5.096

Variable	Value	Coefficient	Variable	Value	Coefficient
Constant		**+ 3.6**	**Sex**	female	**+ 0.2**
				male / ???	**0**
Worst injury	AIS 3	**- 0.5**	**ASA pre-trauma**	1-2	**+ 0.3**
	AIS 4	**- 1.3**		3 / ???	**0**
	AIS 5	**- 1.7**		4	**- 1.3**
	AIS 6	**- 2.9**	**Mechanism**	blunt / ???	**0**
Second worst injury	AIS 0-2	**+ 0.2**		penetrating	**- 0.6**
	AIS 3	**0**	**GCS motor function**	normal	**+ 0.6**
	AIS 4	**- 0.6**		directed / ???	**0**
	AIS 5	**- 1.4**		non-directed	**- 0.4**
Head injury	AIS 0-2	**0**		none	**- 0.8**
	AIS 3/4	**- 0.1**	**Systolic BP on admission**	< 90	**- 0.7**
	AIS 5/6	**- 0.8**		90-110 / ???	**0**
Age	1-5	**+ 1.4**		111-150	**+ 0.3**
	6-10	**+ 0.6**		> 150	**0**
	11-54	**0**	**CPR**	nein / ???	**0**
	55-59	**- 0.5**		ja	**- 1.8**
	60-64	**- 0.8**	**Coagulation: INR**	< 1.2	**+ 0.6**
	65-69	**- 0.9**		1.2 - 1.4	**+ 0.2**
	70-74	**- 1.2**		1.4 - 2.4 / ???	**0**
	75-79	**- 1.9**		≥ 2.4	**- 0.4**
	80-84	**- 2.4**	**Blood: Hemoglobin**	≥ 12.0	**+ 0.4**
	85+	**- 2.7**		7.0-11.9 / ???	**0**
Pupil reactivity	brisk	**+ 0.2**		<7.0	**- 0.5**
	sluggish / ???	**0**	**Acidosis: Base deficit**	< 6	**+ 0.3**
	fixed	**- 1.0**		6-9 / ???	**0**
Pupil size	normal	**+ 0.2**		9-15	**- 0.4**
	anisocoric / ???	**0**		15+	**- 1.5**
	bilat. dilated	**- 0.5**			

RISC II

uni versität
Witten/Herdecke

Verletzungsmuster

Verletzungen ab AIS ≥ 2

Farbe	Bereich
	70%+
	60-69%
	50-59%
	40-49%
	30-39%
	20-29%
	<20%
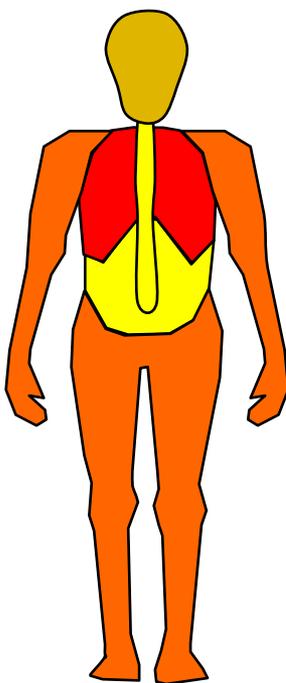
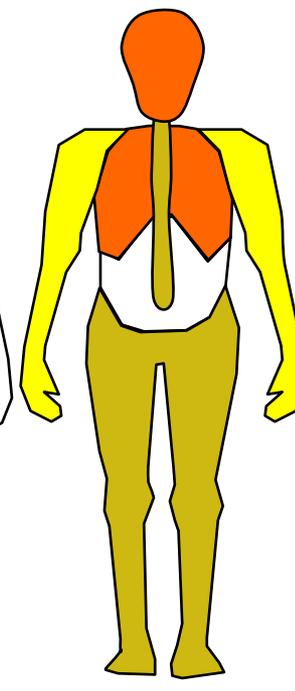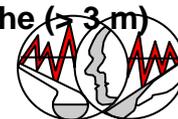**Autofahrer**   **Motorradfahrer**   **Fahrradfahrer**   **Fußgänger**   **Stürze aus geringer Höhe (bis 3 m)**   **Stürze aus großer Höhe (> 3 m)**
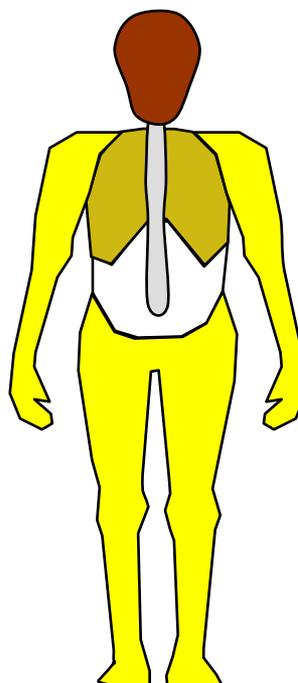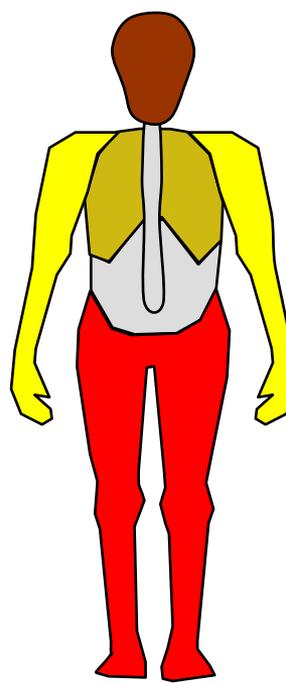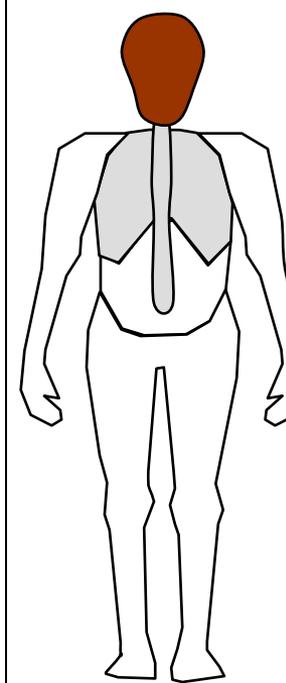
Patienten mit ISS ≥ 9; TraumaRegister DGU, Jahresbericht 2009

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Uhrzeit der Krankenhausaufnahme
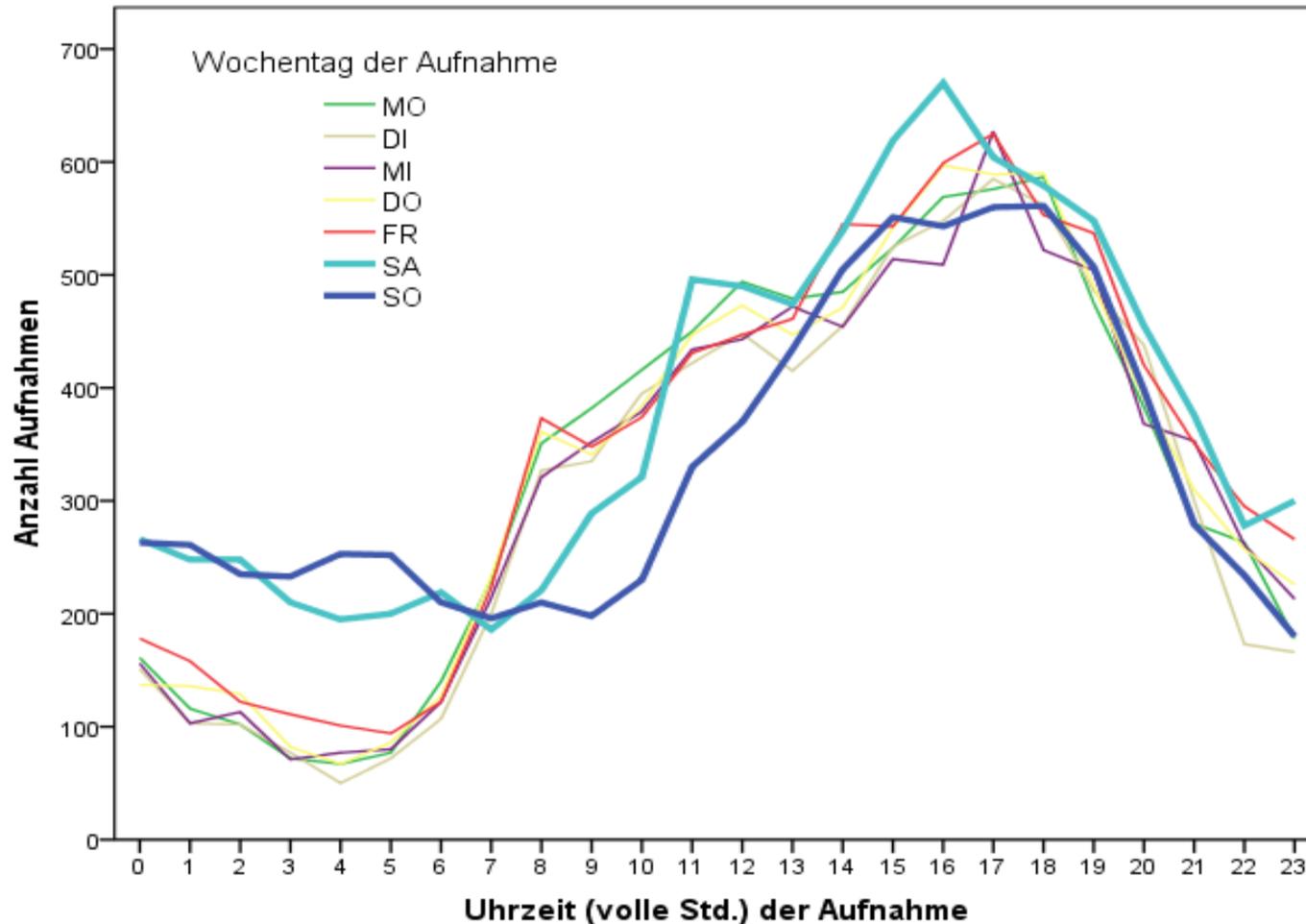
Alter
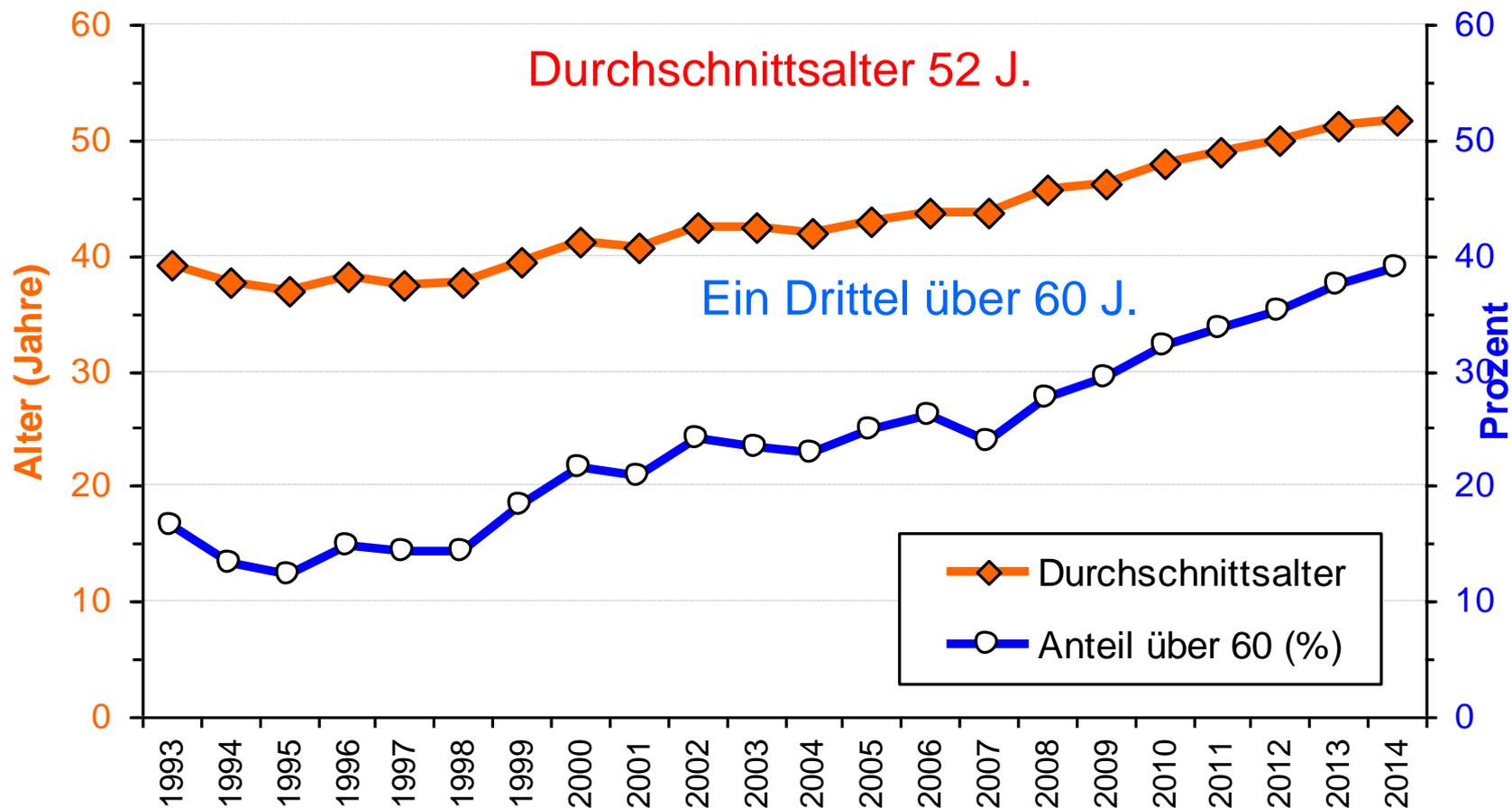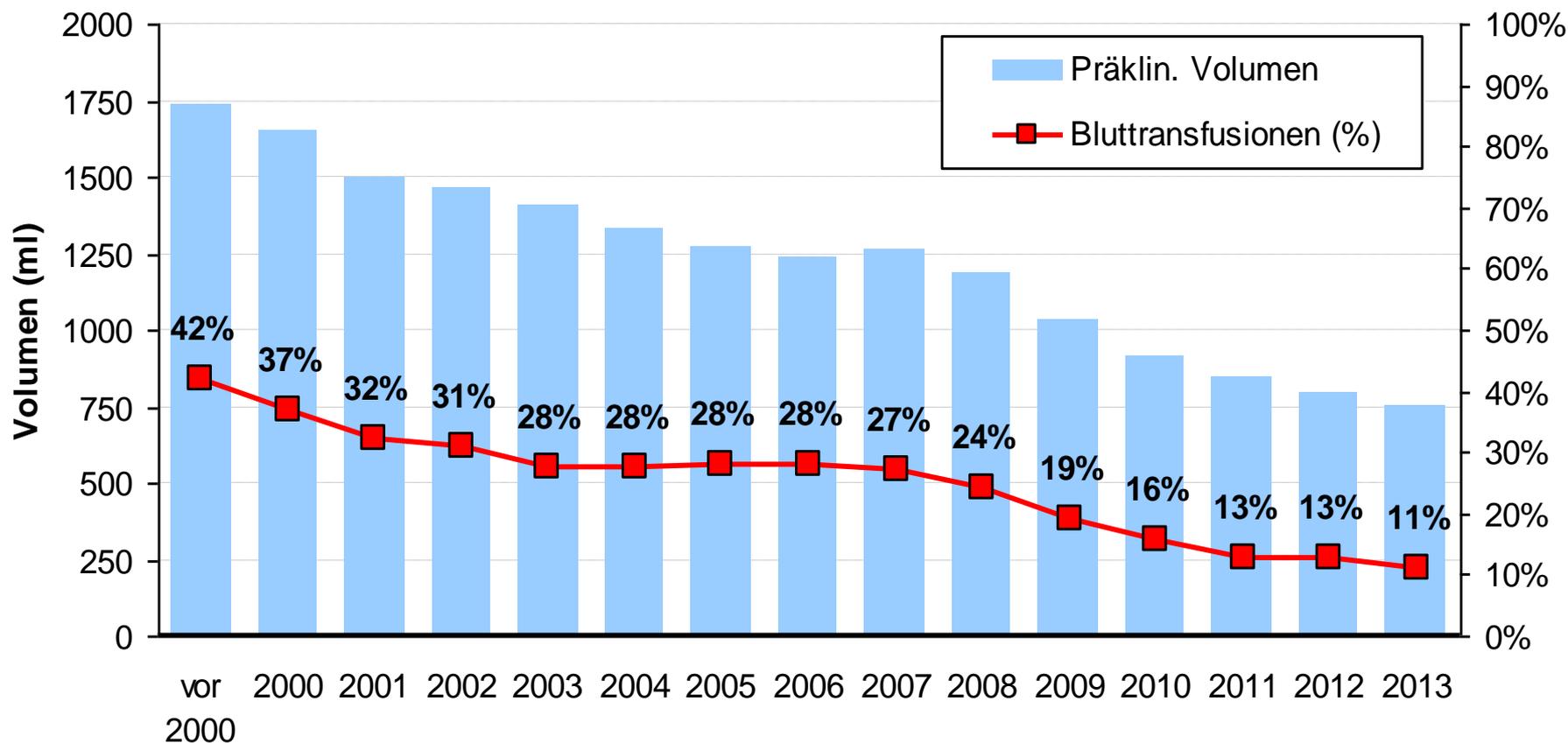
Ziele

Durchführung einer anonymen externen vergleichenden **Qualitätssicherung**

- Rückmeldung; Qualitätsberichte

- Indikatoren

Wissenschaftliche Auswertungen zur Versorgung Schwerverletzter

- Versorgungsrealität

- Epidemiologie; Verletzungen

- Outcome

- Ökonomie

- **Evaluation von Maßnahmen ?**

RCT *versus* Register

	RCT	Register
Vergleichbarkeit	+++	(+)
Datenumfang	+++	(+)
Datenqualität	+++	(+)
Aufwand, Kosten	+++	+
Repräsentativität	+	+++
Qualitätssicherung	--	+++
Epidemiologie	--	+++
Änderungen der Versorgung	--	+++
Struktureffekte	--	+++
Nutzennachweis	+++	?

Wie kann ich in Registerdaten „**Vergleichbarkeit**" herstellen?

- Parallelisieren

- Subgruppenanalysen

- Matched Pairs

- Outcome-Adjustierung

- Propensity Score

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Auswertestrategien

Intervention A

Intervention B

R. Lefering: Strategies for comparative analysis of registry data.
Injury 2014, 45 (Suppl.3): S83-S88
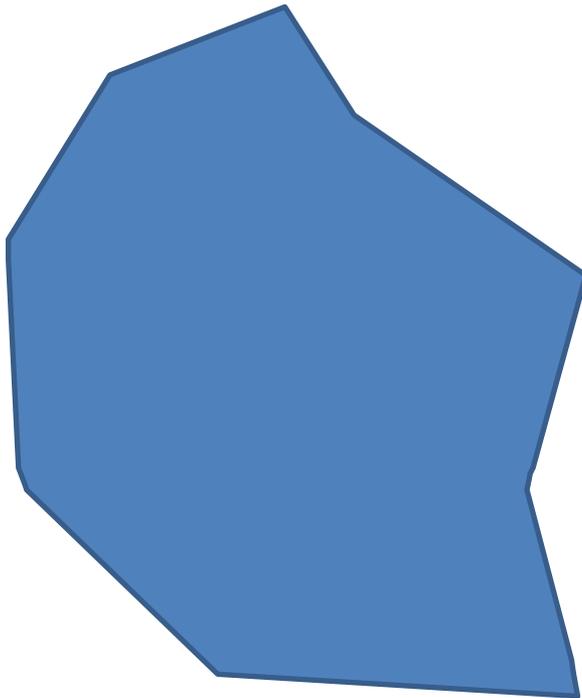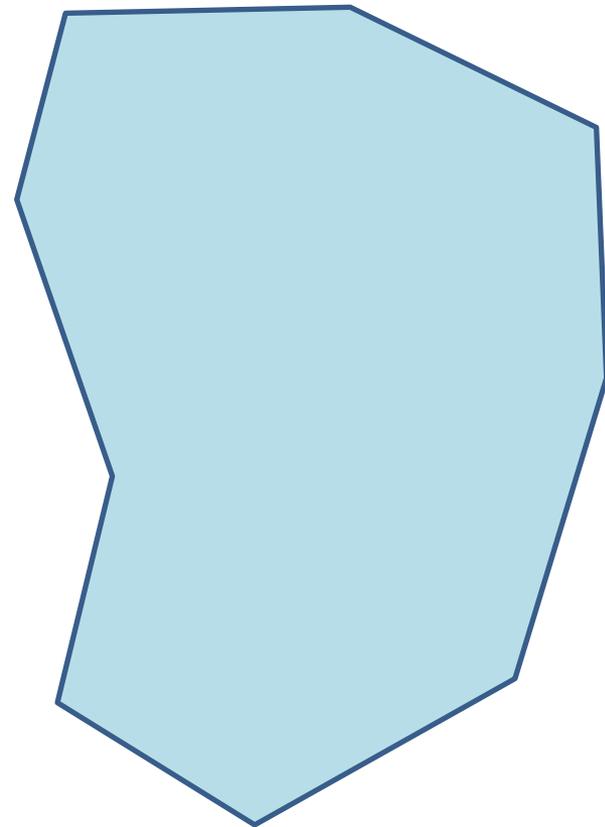
„Parallelisieren"

Intervention A Intervention B

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„**Subgruppenanalysen**"

Intervention A

Intervention B

R. Lefering: Strategies for comparative analysis of registry data.
Injury 2014, 45 (Suppl.3): S83-S88

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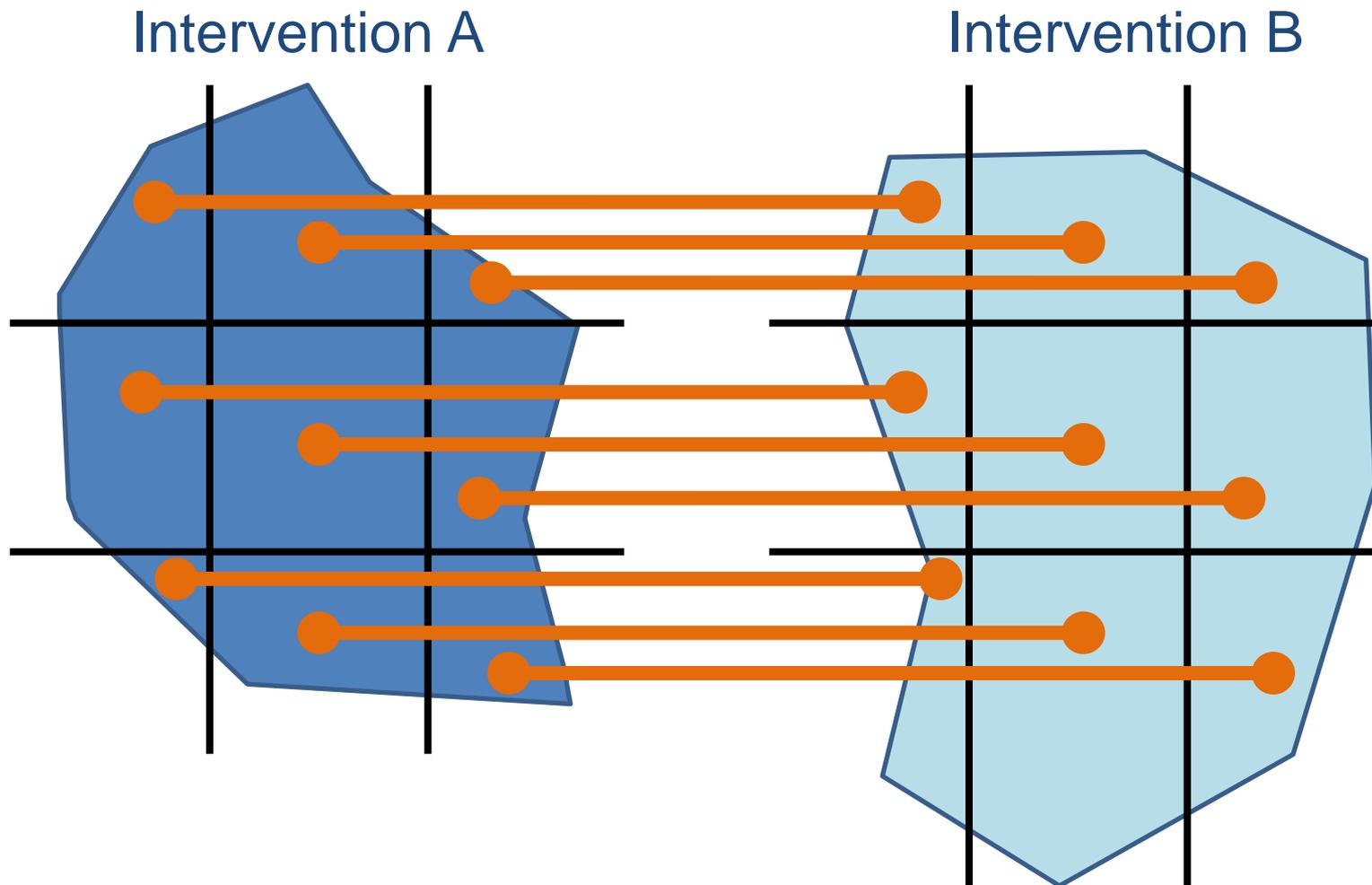
„Matched Pairs"

Intervention A

Intervention B

Institut für Forschung in der
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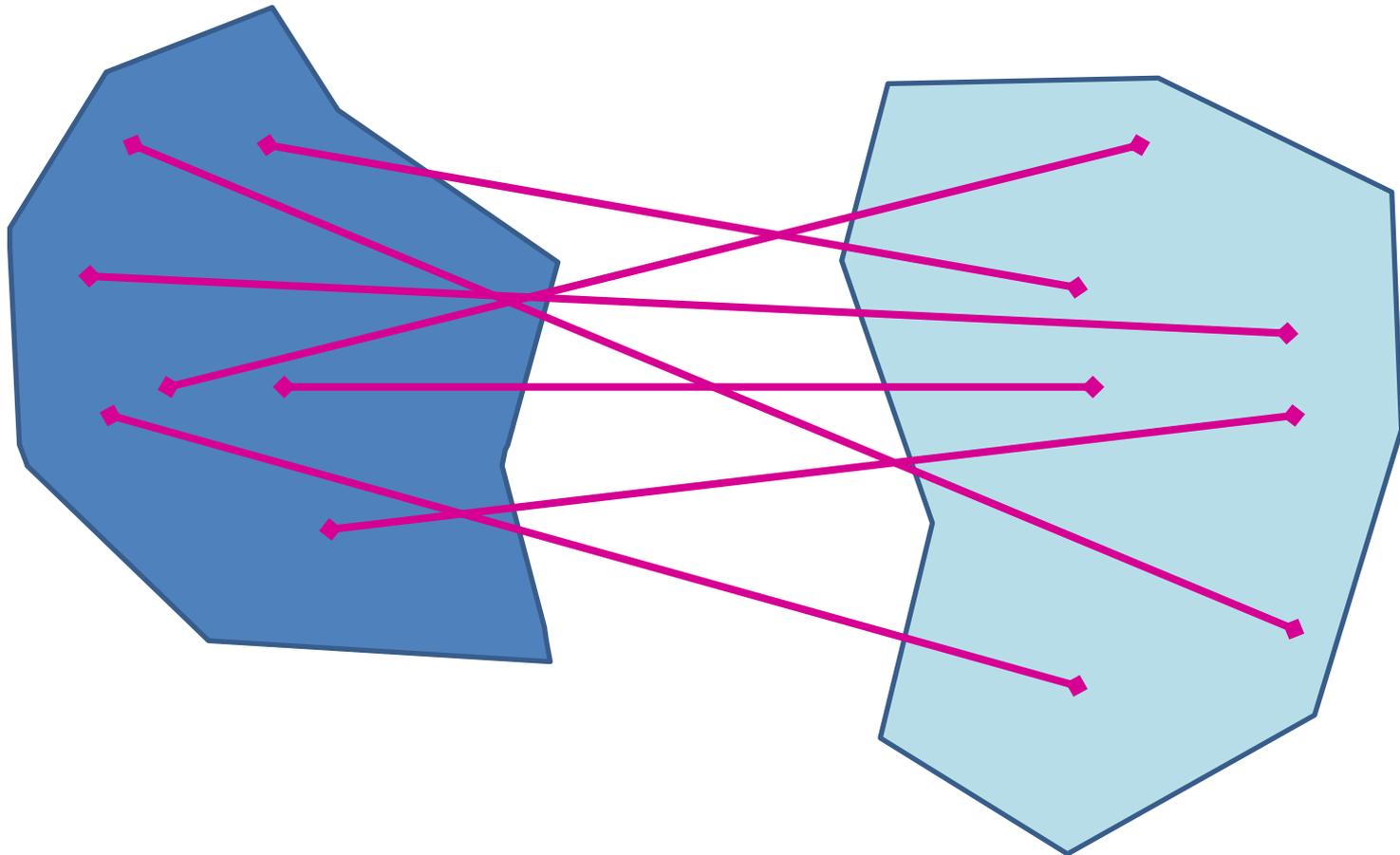
„Outcome-adjustierte Vergleiche"

Intervention A

Intervention B

Beobachtetes Outcome

Erwartetes Outcome

Beobachtetes Outcome

Erwartetes Outcome

R. Lefering: Strategies for comparative analysis of registry data.
Injury 2014, 45 (Suppl.3): S83-S88

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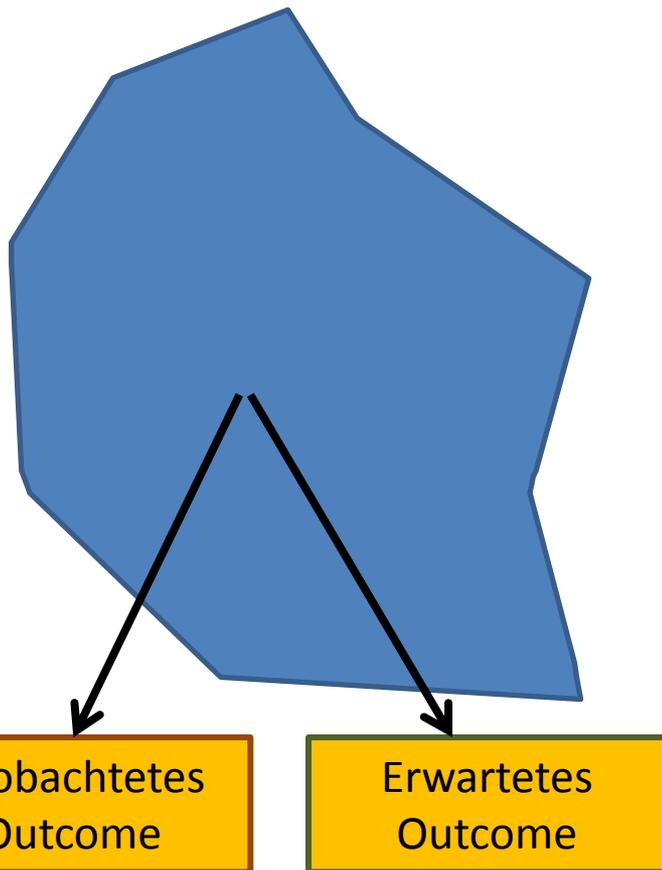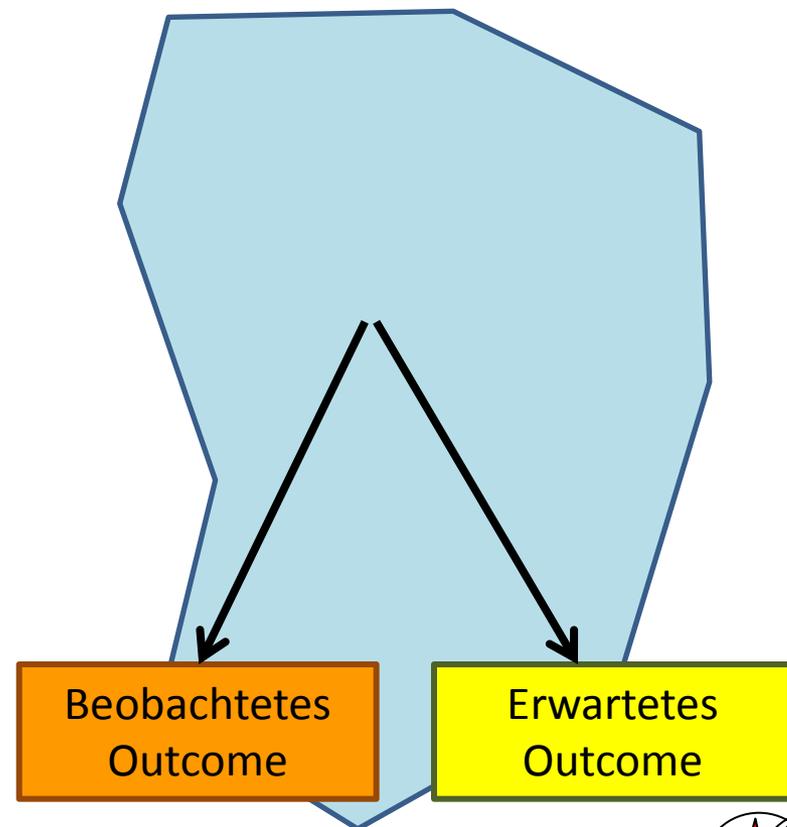
Propensity-Score Analysen

R. Lefering: Strategies for comparative analysis of registry data.
Injury 2014, 45 (Suppl.3): S83-S88

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Drei Beispiele

1. Ganzkörper-CT

2. Präklinische Volumengabe

3. Damage Control Surgery

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Computer-Tomographie (CT)

Bildquelle:
wikipedia.org

Bildquelle: www.jnch.nic.in/infra.htm

Effect of whole-body CT during trauma resuscitation on survival

2002-2004

Ganzkörper-CT
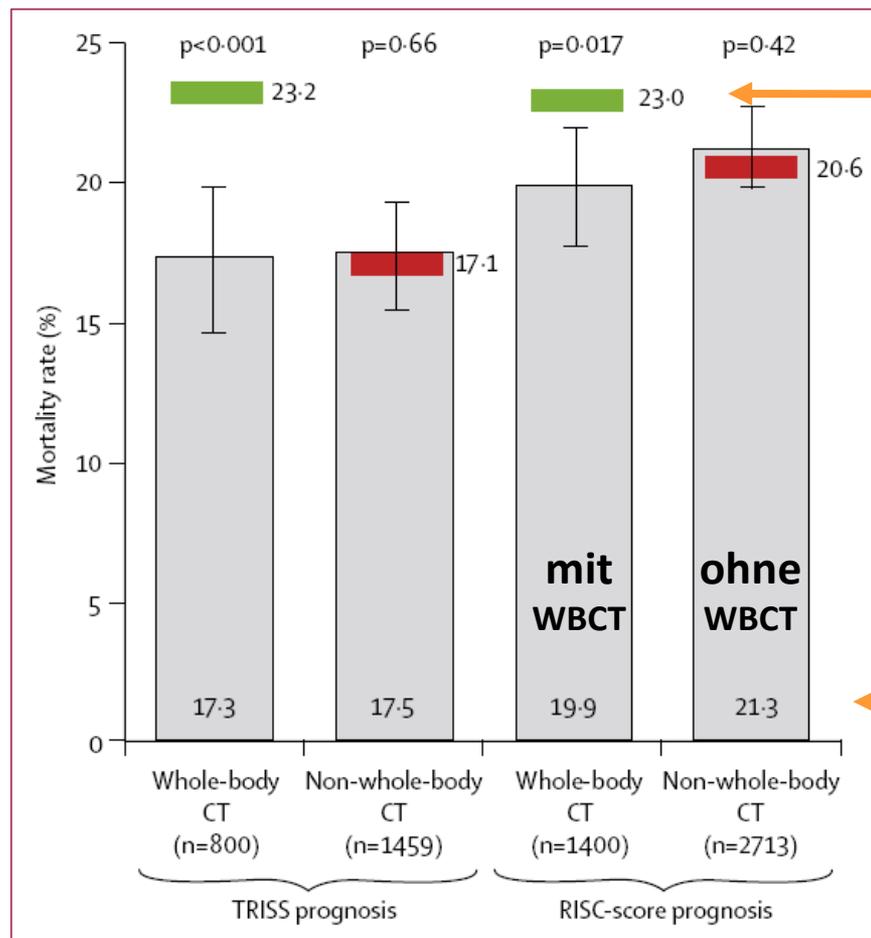
RISC Prognose

Letalität

Huber-Wagner, Lefering, et al. „Effect of whole-body CT during trauma resuscitation on survival: a retrospective multicentre study" *Lancet* 2009

Registerergebnisse zur Nutzenbewertung?

	Regression coefficient β	p value	Odds ratio (e^β; 95% CI)
RISC score*	0·92	<0·001	2·50 (2·35–2·66)
Whole-body CT	−0·38	0·001	0·69 (0·55–0·85)
Level			
I (reference)	..	0·96	..
II	0·11	0·93	1·01 (0·79–1·30)
III	−0·12	0·81	0·89 (0·35–2·29)
Year			
2002 (reference)	..	0·68	..
2003	0·06	0·62	1·06 (0·84–1·35)
2004	−0·05	0·70	0·95 (0·75–1·22)
Constant	−0·02	0·82	..

RISC=revised injury severity classification. *Inverse logistic transformation of the RISC-score-predicted probability of death.

Table 5: Logistic regression model 4 (RISC+whole-body CT+level of hospital+year) based on data from 4113 patients

Huber-Wagner, Lefering, et al. „Effect of whole-body CT during trauma resuscitation on survival: a retrospective multicentre study" *Lancet* 2009

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Immortal
Time Bias

To eliminate this potential bias, we recalculated our results excluding all patients who died within the first hour after hospital admission (mean time to whole-body CT was 35 min, see table 2 of the original paper). In fact those early deaths were more common in the non-whole-body CT group (n=58 vs n=8). However, these patients also had a very bad prognosis: the average predicted mortality rate was 75%. Thus exclusion of these cases lowered both predicted and observed mortality rates in the non-whole-body CT group (observed 19·6% vs expected 19·4%, based on the revised injury severity classification score), whereas the results in the whole-body CT group remained virtually unchanged (19·5% vs 22·7%, respectively).

Authors' reply
We agree with Frank Andersohn that immortal time bias could have affected our study. He is right in stating that patients who received whole-body CT had to su⌐
the procedure was done. However,

Huber-Wagner, Lefering, et al. „Effect of whole-body CT during trauma resuscitation on survival: a retrospective multicentre study" *Lancet* 2009

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Ganzkörper-CT

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Ganzkörper-CT

- bei Kindern ?

- bei speziellen Verletzungen ?

- im Schock ?

- Wo steht das Gerät ?

- Schockraum-Algorithmen ?

S. Huber-Wagner et al. / Injury, 45S (2014) S76–S82

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Ganzkörper-CT

13 „Multislice-First" Kliniken 2002-07

	WB-CT first	WB-CT later	Standard
	0,72	0,82	0,80
Letalität	12,6	13,7	14,3
Prognose (RISC)	17,5	16,8	17,8
	n=587	n=322	n=168

Legend: ■ Letalität ■ Prognose (RISC)

Lefering et al., European Congress for Trauma & Emergency Surgery, Basel 2012

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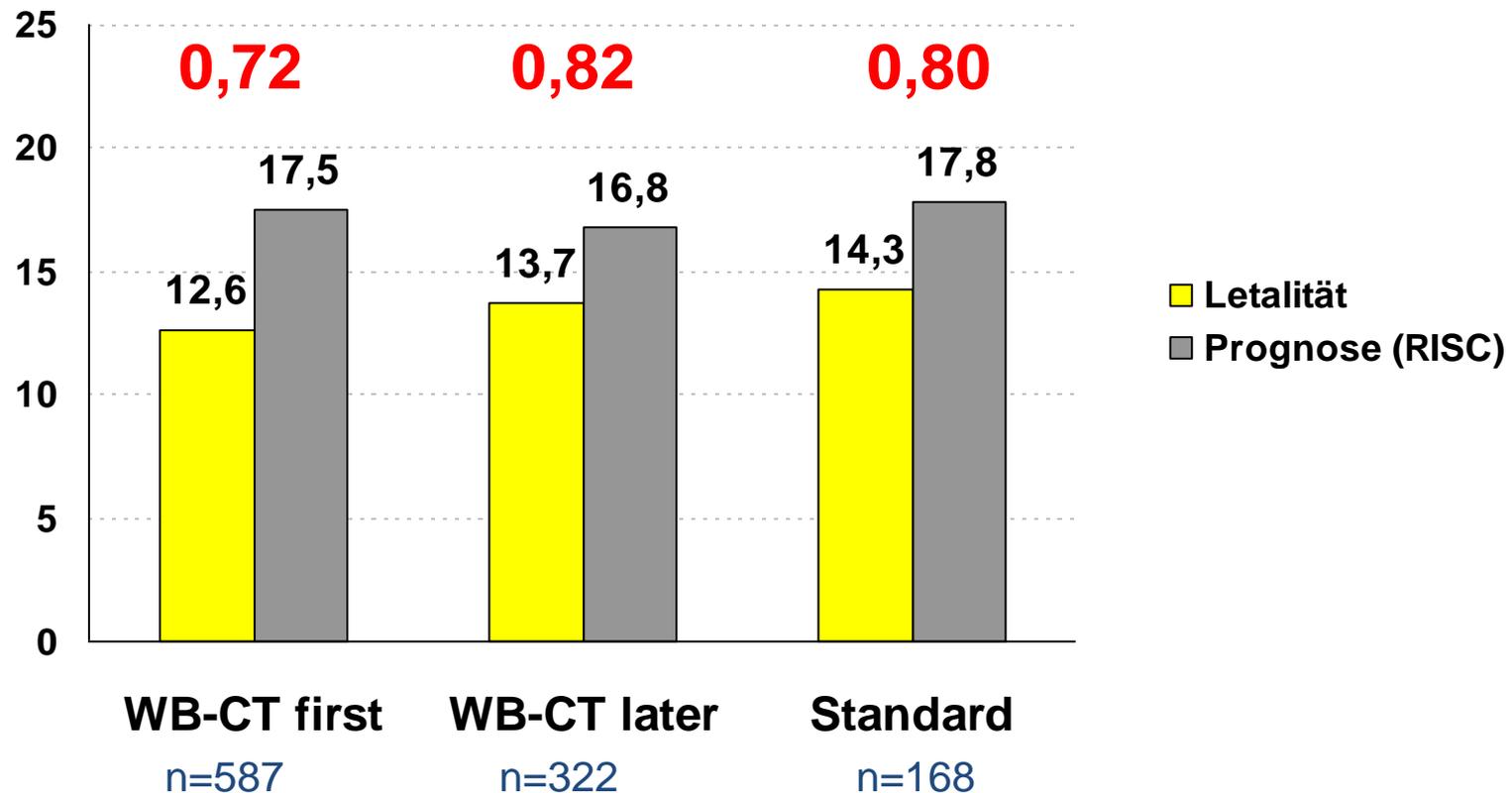
Präklinische Volumentherapie

👍 Blutdruckkorrektur   👎 Blutverdünnung

👍 Schnell wirksam   👎 Coagulopathie

👍 Kreislauf   👎 Hypothermie

👍 Organperfusion   👎 Transfusionen

Registerergebnisse zu

Pseudo-Randomisierung

Tagesdatum
gerade / ungerade

Bickell WH et al.
„Immediate versus delayed fluid resuscitation for hypotensive patients with penetrating torso injuries"
New Engl. J. Med. (1994)
331: 1105-9

Table 1. Characteristics of 598 Patients with Penetrating Torso Injuries Who Received Immediate or Delayed Fluid Resuscitation.*

CHARACTERISTIC	IMMEDIATE RESUSCITATION (N = 309)	DELAYED RESUSCITATION (N = 289)
Age (yr)	31±11	31±10
Male sex (% of patients)	88	91
Systolic blood pressure (mm Hg)	58±35	59±34
Injury Severity Score	26±14	26±14
Revised Trauma Score	5.4±2.1	5.6±2.1
Probability of survival	69	72
Mechanism of injury (% of patients)		
Gunshot wound	65	67
Stab wound	29	30
Shotgun-blast wound	6	3
Primary site of surface injury (% of patients)		
Neck	5	3
Chest	33	35
Abdomen	63	62
Patient care times (min)		
Response interval	8±5	8±6
Scene interval	9±8	7±6
Transport interval	13±6	12±6
Trauma-center interval	44±65	52±99
Intraoperative interval	114±105	134±101†

*Plus–minus values are means ±SD.

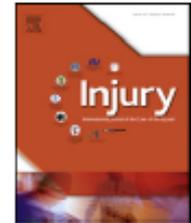†P = 0.028 for the comparison between groups.

Pre-hospital Volume

Contents lists available at SciVerse ScienceDirect

Injury

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

Does increased prehospital replacement volume lead to a poor clinical course and an increased mortality? A matched-pair analysis of 1896 patients of the Trauma Registry of the German Society for Trauma Surgery who were managed by an emergency doctor at the accident site

Bjoern Hussmann [a,*], Rolf Lefering [b], Christian Waydhas [a], Alexander Touma [a], Max D. Kauther [a], Steffen Ruchholtz [c], Sven Lendemans [a]

the Trauma Registry of the German Society for Trauma Surgery

[a] Trauma Surgery Dept., University Hospital Essen, Germany
[b] Institute for Research in Operative Medicine (IFOM), Faculty of Medicine, Witten/Herdecke University GmbH (A Non-Profit, Limited-Liability Company), Cologne Merheim Medical Centre, Germany
[c] Trauma Dept., Hand and Reconstructive Surgery Unit, University Hospital Marburg, Germany

Hussmann et al. *Injury* (2013) 44: 611–617

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Pre-hospital Volume

- Matched-pairs analysis

- Patients with blood transfusion

- Matched for:
  - injury pattern (5 body regions)
  - year of trauma
  - blood pressure
  - age group

- Pre-hospital volume:
  Low: 0-1500 ml / High >1500 ml

- 948 pairs (1896 patients)

Hussmann et al. *Injury* (2013) 44: 611–617

Bleeding or Volume?

Table 3

Clinical course and outcome of patients receiving low- or high-volume prehospital replacement therapy after trauma and bleeding.

Patient characteristics	Values for low- and high-volume groups			
	Low-volume (0–1500 ml)	High-volume (≥1501 ml)	Group mean (all patients)	p-Values
SURG (%)	90.6	88.9	89.8	0.23
Transfer from ED (%)				
Emergency surgery	11.4	13.0	12.2	
Early operation	74.6	73.6	74.1	
ICU	11.2	11.2	11.2	
others (e.g. died in ED)	2.7	2.1	2.4	
Stay in intensive care unit (%)	94.5	92.5	93.5	0.08
Days in the intensive care unit (mean, SD)	18.0 (SD 25.2)	16.1 (SD 16.3)	17.1 (SD 20.1)	0.054
Days intubated (mean, SD)	11.9 (SD 17.6)	11.2 (SD 13.9)	11.6 (SD 15.8)	0.29
Ventilator-free days (per the first 30 ICU days; mean, SD)	14.1 (SD 11.6)	12.9 (SD 11.7)	13.6 (SD 11.7)	0.03
ICU-free days (per 30 ICU days; mean, SD)	10.2 (SD 10)	9.1 (SD 10)	9.7 (SD 10)	0.02
Organ failure (%)	60.8	62.7	61.7	0.44
Multiple organ failure (%)	41.6	41.8	41.7	0.93
Sepsis (%)	15.8	17.0	16.4	0.5
RISC prognosis (%)	23.4	27.2	25.3	0.01
TRISS prognosis (%)	28.9	29.5	29.2	0.62
Died in hospital (%)	22.7	27.6	25.1	0.01
Died within the first hour (%)	0.6	0.3	0.5	0.32
Died within the first 6 h (%)	10.8	15.0	12.9	0.001
Died within the first 24 h (%)	13.2	17.3	15.2	0.01
Days of hospitalisation (mean, SD)	36.1 (SD 37.5)	33.8 (SD 33.5)	35 (SD 35.5)	0.15

Values shown as mean, standard deviation (SD) or % of the group. ED, emergency department; SURG, surgery; ICU, intensive care unit; RISC, Revised Injury Severity Classification; TRISS, Trauma and Injury Severity Score.

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Bleeding or Volume?

	Low volume	High volume
ISS	35.1	34.8
Age (y)	39.4	30.0
Pre-hospital volume (ml)	**1110**	**2649**
Pre-hospital time	68.5	68.7
BP on admission	112	111
Mass transfusion (%)	22.6%	28.3%
pRBC (units)	7.0	8.3
FFP (units)	3.8	5.0
Vent-free days	14.1	12.9
Mortality	**22.7%**	**27.6%**

Table 3
Clinical course and

Patient characteri

p-Values

SURG (%)
Transfer from ED
  Emergency surg
  Early operation
  ICU
  others (e.g. died
Stay in intensive c
Days in the intens
Days intubated (n
Ventilator-free da
ICU-free days (per
Organ failure (%)
Multiple organ fai
Sepsis (%)
RISC prognosis (%
TRISS prognosis (
Died in hospital (
Died within the fi
Died within the fi
Died within the fi
Days of hospitalis

0.23

0.08
0.054
0.29
0.03
0.02
0.44
0.93
0.5
0.01
0.62
0.01
0.32
0.001
0.01
0.15

Values shown as m
Classification; TRISS, Trauma and Injury Severity Score.

jury Severity

Hussmann et al. *Injury* (2013) 44: 611–617

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Mortality	**22.7%**	**27.6%**
Prognosis (RISC)	23.4%	27.2%

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Damage Control *versus* Early Total Care

- Primärschaden = Unfall

- Sekundärschaden = OP

- Damage Control = Operativen Sekundärschaden minimieren

- Early Total Care = direkte Versorgung der Verletzungen

Fixateur Externe

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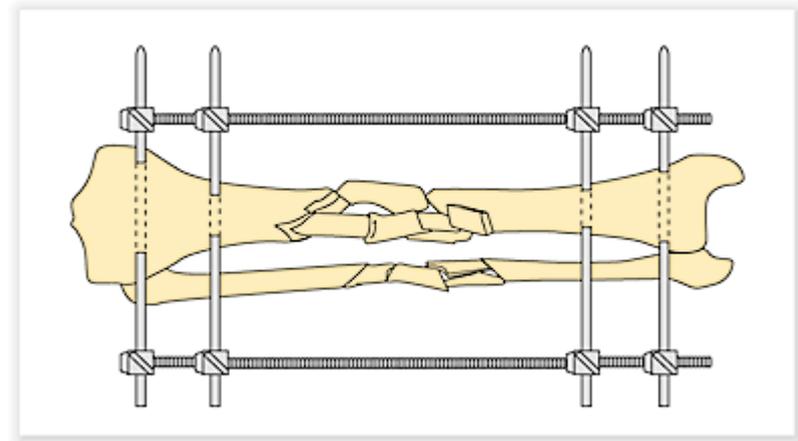
Damage Control *versus* **Early Total Care**

- TraumaRegister DGU®:
Vorteil für Damage Control

- Literatursuche (bis 2002):
positiv

- Randomisierte Studie
geplant / gestartet

- Wegen Rekrutierungs-
problemen abgebrochen

- TR-DGU: Auswertung wegen fehlender
Vergleichsgruppe nicht mehr möglich

The Journal of **TRAUMA** Injury, Infection, and Critical Ca

Evaluation of Criteria for Temporary External Fixation in Risk-Adapted Damage Control Orthopedic Surgery of Femur Shaft Fractures in Multiple Trauma Patients: "Evidence-Based Medicine" versus "Reality" in the Trauma Registry of the German Trauma Society

BioMed Central

Trials

Open Access

Study protocol

Protocol for a randomized controlled trial on risk adapted damage control orthopedic surgery of femur shaft fractures in multiple trauma patients

Dieter Rixen*[1], Eva Steinhausen[1], Stefan Sauerland[2], Rolf Lefering[2], Matthias Meier[3], Marc G Maegele[1], Bertil Bouillon[1] and Edmund AM Neugebauer[2]

Address: [1]Department of Trauma and Orthopedic Surgery, University of Witten-Herdecke at the Hospital Cologne-Merheim, Ostmerheimer Str. 200, 51109 Cologne, Germany, [2]Institute for Research in Operative Medicine, University of Witten-Herdecke, Ostmerheimer Str. 200, 51109 Cologne, Germany and [3]Department for Trauma, Hand and Reconstructive Surgery, University of Cologne, 50937 Cologne, Germany

Email: Dieter Rixen* - RixenD@kliniken-koeln.de; Eva Steinhausen - SteinhausenE@kliniken-koeln.de; Stefan Sauerland - Stefan.Sauerland@ifom-uni-wh.de; Rolf Lefering - Rolf.Lefering@ifom-uni-wh.de; Matthias Meier - Matthias.Meier@uk-koeln.de; Marc G Maegele - MaegeleM@kliniken-koeln.de; Bertil Bouillon - BouillonB@kliniken-koeln.de;

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Zusammenfassung

Register können …

    - die Versorgungsrealität gut abbilden,

    - zeitliche Veränderungen belegen,

    - wertvolle epidemiologische Daten liefern,

    - als Basis für eine externe Qualitätssicherung dienen,

    - die Implementation von Versorgungsstrukturen begleiten

Zusammenfassung

Register können bedingt …

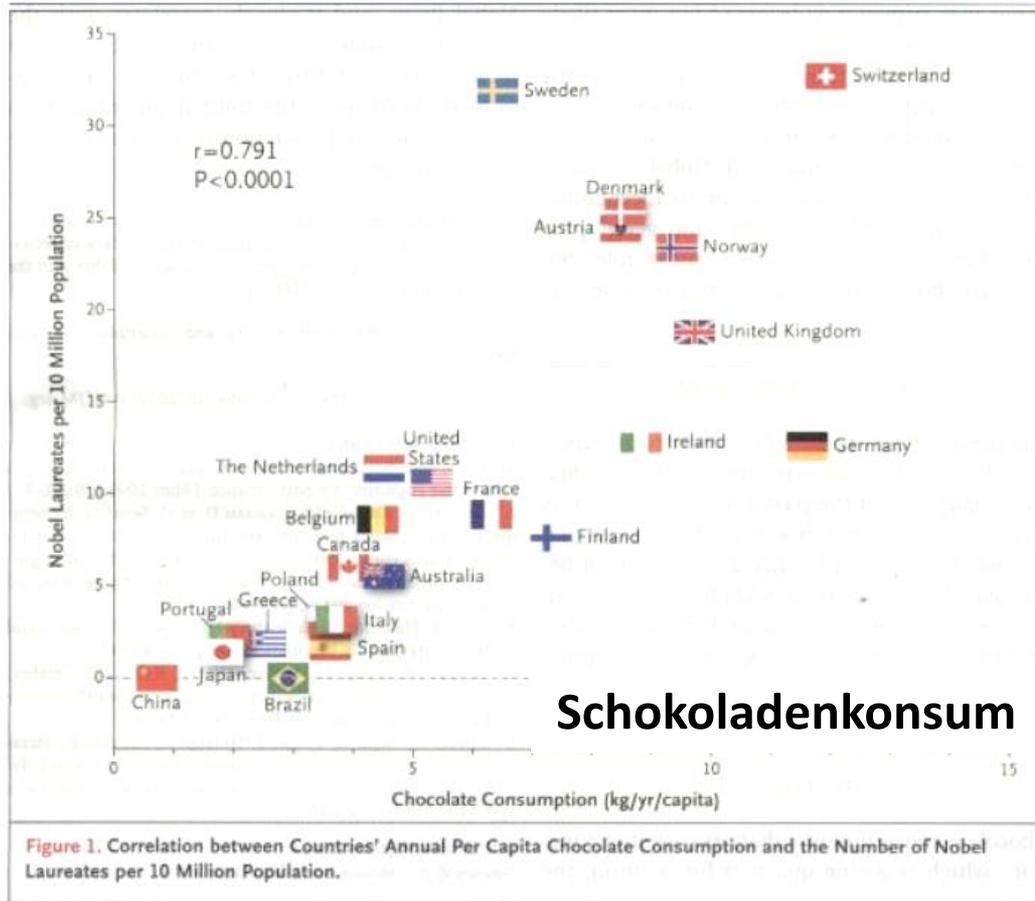   - zu Wirksamkeits-Prüfungen herangezogen werden.

Voraussetzungen:

➢ Randomisierte Studien sind kaum/nicht möglich,

➢ Relevanten Confounder werden erfasst (Adjustierung),

➢ Vergleichbare Situationen sind vorhanden,

➢ Hohe Datenqualität

Vorsicht bei kausalen Interpretationen!

Nobelpreisträger

Schokoladenkonsum

Figure 1. Correlation between Countries' Annual Per Capita Chocolate Consumption and the Number of Nobel Laureates per 10 Million Population.

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