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How health service delivery guides the allocation of major trauma patients in intensive care units of the inclusive (Hub & Spoke) trauma system of the Emilia Romagna Region (Italy): a cross sectional study

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How health service delivery guides the allocation of major trauma patients in intensive care units of the inclusive (Hub & Spoke) trauma system of the Emilia Romagna Region (Italy): a cross sectional study

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Abstract

<u>Objective</u>: to evaluate the cross sectional patient distribution in the intensive care units of the inclusive hub and spoke trauma systems of the Emilia Romagna Region, Italy

<u>Setting</u>: Intensive care units of Trauma System of the Emilia-Romagna, an Italian region with about 4.5 million inhabitants.

<u>Participants</u>: The case material consisted of 5,300 patients with an Injury Severity Score >15, admitted in the regional intensive care units, and recorded in the Regional Severe Trauma Registry between 2007 and 2012. Patients excluded was those never admitted to an intensive care unit or with an Injury Severity Score <15. Severity and typology were classified by the Abbreviated Injury Score in patients with relevant a) traumatic brain, b) multiple injuries, c) extracranial lesions. The trauma systems were divided by those including at least one neurosurgical Level II trauma center (TC) toward those having a neurosurgical service only inside the Level I TC.

 <u>Results:</u> More than half (2988/5287, 56.5%) were admitted to Level I TC but 32.2% (1702/5287) were admitted to Level II neurosurgical TC.

The rate (in respect of all the trauma patients of the SIAT) of patients admitted to the Level I TC head of a SIAT without further neurosurgical facilities (1083/1472, 73.6%) was higher than in the Level I TCs head of the Trauma Systems including further neurosurgical Level II TC (1905/3815; 49.9%). In the Trauma Systems with level II neurosurgical TC the fraction of patients admitted to level I TCs (1905/3815; 49.9%) was similar to those admitted to the level II neurosurgical TC (1702/3815, 44.6%).

<u>Conclusion:</u> The concept of Hub and Spoke system was fully applied only in the Trauma System where the neurosurgical facilities was an exclusive finding of the Level I TC. This study suggests that the regional density of neurosurgical centers must be considered before implementing Trauma Systems.

Article summary. Strengths and limitations of this study

Patient centralization is *per se* largely driven by the availability of neurosurgical facilities.

The construction of a hub-and-spoke system in a public health system involves limiting the number of neurosurgical centers ready for traumatic emergencies governance.

The study results are limited by the inclusion of only the patients admitted to an intensive care unit

Abstract words count 300

Manuscript words count 2112

Background

Trauma is a major issue for society and a challenge for health policy makers. In Italy it is chiefly associated with road accidents (ISTAT, ETSC). [1-4] Regionalized trauma systems have been designed in many countries to provide a coordinated, organized response to injury- [5] By concentrating patients in a few Level I trauma centers (TC) to ensure prompt, specialized care should improve patient outcomes.[6] Health authorities in several countries have used guidelines to designate hospitals as level I through IV TCs.[6] There is a general consensus that Level I TCs should admit at least 200 patients with major trauma per year.[5,7]

Currently most regional trauma systems in the United States are based on the "exclusive" design. However this precludes the participation of non-TC acute care facilities in the treatment of less severe trauma patients and thereafter the expertise of non TCs could fall below critical levels.

By contrast, in Europe, which is more urbanized and has a higher density of hospitals, an "inclusive" model is more frequently adopted, encompassing non-TC hospitals (spoke centers) caring chiefly for less severe trauma.[8] In this system, Level 1 TCs (hubs) are central to trauma system organization.[8] They directly admit the patients who are most severe at the scene and indirectly receive those who are too severe at first admission or who deteriorate after admission to spoke centers.

In 2002, the regional health service of Emilia Romagna, in the north of Italy, designed three trauma systems, headed by three Level I TCs, based on geographic location, previous organization history, and presence of clinical expertise (DGR 1267/2002).[9] Each trauma system is named "Sistema Integrato Assistenza Traumi (SIAT, Integrated System for Trauma Patient Care)", each of which represents a separate, specific Trauma System. In two of these Trauma Systems, in addition to level I TC, were also concomitantly present level II TCs neurosurgical centers. Considering the relevance of TBI on trauma patients there could be that these latter centers centralize patients otherwise potentially deputy for level I TC.

The aim of this study was to describe, ten years after the establishment of the Regione Emilia Romagna Trauma System, the access of patients with major trauma to the intensive care units (ICUs) in the different Trauma System and how the availability of neurosurgical facilities could had influenced this process.

Material and Methods

Setting: Emilia-Romagna is an Italian region with about 4.5 million inhabitants. (Figure 1 and online supplement appendix table 1).[10] The "inclusive" model of trauma care included community or teaching hospitals not dedicated exclusively to trauma. All were connected by a dedicated Emergency Medical Service, including a helicopter. The characteristics of Trauma Center are described in the Appendix (Appendix Table 2).[6] The underlying philosophy of the inclusive hub and spoke trauma system is that Level I TCs function as hubs within highly specialized hospitals and other Level II TC facilities serve as "spokes". Some Level II TCs have neurosurgical units. The SIATs differ from each other in that one of them has no neurosurgical Level II unit (Romagna) while the East and West Emilia SIATs have neurosurgical Level II TCs.

In summary, the Trauma System is organized according to:

- a) three subtypes of centre:
- Level I TCs: Bologna, Parma, Cesena hospitals
- Level II TCs with neurosurgery: Modena Baggiovara, Ferrara, Reggio Emilia hospitals
- Level II TCs with no neurosurgery: Rimini, Riccione, Forlì, Ravenna, Faenza, Lugo, Piacenza b) two subtypes of SIAT:

- SIAT with neurosurgical Level II TC;
- SIAT with no neurosurgical Level II TC.

The system embraces the concept of back transferring patients from the hub to the spoke, once they have been stabilized and specialist problems have been solved.[12] The ICU network is further supported by a rehabilitation unit network.[13]

The protocols to describe direct access from the scene to Level I TC and secondary referral from level II TC were designed in each of three Trauma Systems. However, Romagna first implemented the telemedicine for traumatic brain injury since the 1990s.[14-15]

Since 2007, data on the severity of patients admitted to hospitals in the Emilia Romagna region have been prospectively collected by the three TCs and by ten other spoke hospitals in the regional severe trauma registry (Registro Regionale Traumi Gravi, RRTG).[16,17] The system has been regularly monitored by a commission which checks data and implements the system organization.[18]

Case material

The cross sectional study was conducted using data from the RRTG. The case material analyzed for the study consisted of consecutive cases collected from 2007 to 2012 (appendix figure 1). The criteria for inclusion in the registry was traumatic injury with an Injury Severity Score (ISS) greater than 15 or admission to an ICU.[19] Consequently a potential bias is that patients not admitted in the regular ward were not considered by the study. Injury severity was coded according to the Abbreviated Injury Score 1990 (AIS) – 1998 update, by a trained coder at each hospital. Training was self-managed by the regional authorities, with no official certification by the Association for the Advancement of Automotive Medicine.[20]

Descriptive analysis of patient distribution

Patients can be transferred from one hospital to another within the trauma system but are recorded in the registry only once. The following attribution criteria are applied for registry entries: a) the first admitting hospital, b) the data recorded in the ward providing the most intensive therapy, in the said hospital.

Patients were also classified in three categories by type of anatomical lesion. The objective was to identify patients with relevant extracranial injuries, those with relevant cranial or spinal injuries, and those with both clinically relevant extracranial or cranial/spinal injuries.

We used a priori AIS cutoff of ≤ 3 and ≥ 3 to classify, respectively, relevant or not clinical lesion.

AIS cranial score ≥3 was used to classify moderate or severe TBI,[21-24] although this differs from the conventional classification.[26.27]

Accordingly, the patients were classified as follows:

- patients with <u>severe multiple injuries</u>: with extracranial and cranial lesions both having AIS score ≥ 3.
- patients with <u>extracranial lesions</u>: with at least one extracranial AIS score of ≥ 3 and a cranial AIS of < 3,

Demographic and clinical characteristics of patients were also described by Abbreviated Injury Score (AIS),[19] Glasgow Coma Scale (GCS),[24] Injury Severity Score (ISS),[18] Comorbidities were assessed by Charlson Score Index.[26]

The data were analyzed descriptively. Continuous variables were expressed as mean, standard deviation, median and range. All analyzes are carried out through SAS 8.2 System (SAS Institute, North Carolina). Because of the observational design of the study and the anonymity of the final database, neither patient consent nor approval of ethical committee was necessary.

Results

After applying the inclusion criteria, 5,300 patients were eligible for the study. However, details on the AIS categories were available for only 5,287 patients.

General and specific characteristics of patients (reported in Table 1).

Table 1: Case material on 5300 patients in the period 2007-2012. Data on type of referral are limited to 5293 patients (missing data on 7 patients concerning type of admission). Comorbidities were assessed by Charlson Score Index²⁶. Abbreviated Injury Score (AIS)¹⁹, Glasgow Coma Scale (GCS)²⁴, Injury Severity Score (ISS)¹⁸, Trauma Center (TC). Traumatic Brain Injury (TBI),

Variable	Classification	Trauma System	TC level I (Hub) and direct admis sion	TC level I (Hub) and second ary referr al	Neurosu rgical TC level II (Spoke) and direct admissio n	Neurosu rgical TC level II (Spoke) and secondar y admissio n	Non- neurosur gical TC level II (Spoke)
No.		5300	*2,274 (43- 1%)	*716 (13.5 %)	*1,600 (30.2%)	*102 (1.9%)	**600 (11.3%)
Age, Median (IQR		46 ± 38	44 ± 38	48 ± 39	47 ± 37	56,5 ± 39	49 ± 41
Age, No (%)	0-2	34 (0.6%)	17 (0.7%)	14 (2.0%)	2 (0.1%)	-	1 (0.2%)
	3-8	61 (1.2%)	35 (1.5%)	14 (2.0%)	7 (0.4%)	-	5 (0.8%)
	9-11	33 (0.6%)	21 (0.9%)	4 (0.6%)	4 (0.2%)	1 (1.0%)	3 (0.5%)
	12-14	72 (1.4%)	34 (1.5%)	9 (1.3%)	20 (1.2%)	2 (2.0%)	7 (1.2%)
	15-20	413 (7.8%)	182 (8.0%)	54 (7.5%)	134 (8.4%)	3 (3.0%)	39 (6.5%)

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Variable	Classification	Trauma System	TC level I (Hub) and direct admis sion	TC level I (Hub) and second ary referr al	Neurosu rgical TC level II (Spoke) and direct admissio n	Neurosu rgical TC level II (Spoke) and secondar y admissio n	Non- neurosur gical TC level II (Spoke)
	21-30	792 (14.9%)	363 (16.0 %)	91 (12.7 %)	238 (14.9%)	10 (9.8%)	90 (15.0%)
	31-40	808 (15.2%)	358 (15.7 %)	96 (134. %)	253 (15.8%)	16 (15.7%)	85 (14.1%)
	41-50	791 (14.9%)	355 (15.6 %)	106 (14.8 %)	236 (14.7%)	11 (10.8%)	83 (13.8%)
	51-60	580 (10.9%)	226 (9.9%)	80 (11.2 %)	191 (11.9%)	10 (9.8%)	72 (12.0%)
	61-70	585 (11.0%)	244 (10.7 %)	94 (13.1 %)	180 (11.2%)	14 (13.7%)	53 (8.8%)
	71-80	730 (13.8%)	295 (13.0 %)	108 (15.1 %)	200 (12.5%)	23 (22.6%)	103 (17.1%)
	>80	401 (7.6%)	147 (6.5%)	46 (6.4%)	136 (8.5%)	12 (11.8%)	60 (10.0%)
Gender, No (%)	male	3,905 (73.7%)	1,720 (75.5 %)	512 (71.5 %)	1,182 (73.8%)	68 (66.7%)	421 (70.1%)
Type of trauma, No (%)	Closed	5,160 (97.4%)	2,222 (97.6 %)	695 (97.1 %)	1,573 (95.3%)	100 (98.0%)	567 (94.3%)
	Penetrating	113 (2.1%)	50 (2.2%)	15 (2.1%)	28 (1.7%)	2 (2.0%)	18 (3.0%)
	Missing	27 (0.5%)	5 (0.2%)	6	-	-	16 (2.7%)
Mechanism of injury, No (%)	Traffic	3,517 (66.4%)	1,561 (68.6 %)	370 (51.7 %)	1,107 (69.1%)	50 (49.0%)	427 (71.1%)
	Minor Fall	1,112 (21.0%)	454 (19.9 %)	219 (30.6 %)	324 (20.2%)	37 (36.3%)	77 (12.8%)
	Precipitation	153 (2.9%)	59 (2.6%)	18 (2.5%)	65 (4.1%)	2 (2.0%)	9 (1.5%)
	Crush	129 (2.4%)	54 (2.4%)	15 (2.1%)	34 (2.1%)	1 (1.0%)	25 (4.2%)
	Other	361 (6.8%)	145 (6.4%)	89 (12.4 %)	70 (4.4%)	12 (11.8%)	45 (7.5%)
	Missing	28 (0.5%)	4 (0.2%)	5 (0.7%)	1 (0.1%)	-	18 (3.0%)
Charlson Comorbidity Index ²⁷ , No (%)	0	4,595 (86.7%)	2,035 (89.4 %)	619 (86.5 %)	1,351 (84.4%)	85 (83.3%)	502 (85.5%)
	1	317 (6.0%)	102 (4.5%)	52 (7.3%)	101 (6.3%)	8 (7.8%)	54 (9.0%)

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Variable	Classification	Trauma System	TC level I (Hub) and direct admis sion	TC level I (Hub) and second ary referr al	Neurosu rgical TC level II (Spoke) and direct admissio n	Neurosu rgical TC level II (Spoke) and secondar y admissio n	Non- neurosur gical TC level II (Spoke)
	≥2	388 (7.3%)	140 (6.2%)	45 (6.3%)	149 (9.3%)	9 (8.8%)	45 (7.5%)
ISS, median (IQR)		26 ± 12	26 ± 12	25 ± 12	27 ± 13	25 ± 11	25 ± 14
TBI, No (%)	AISc≥3	1,298 (24.5%)	583 (25.6 %)	319 (44.6 %)	299 (18.7%)	25 (24.5%)	70 (11.6%)
Multiple injury, No (%)	AISc≥3 and AISmax≥3	1,985 (37.4%)	911 (40.0 %)	230 (32.1 %)	650 (40.6%)	30 (39.4%)	164 (27.3%)
Extracranial injury, No (%)	AIS max extracranial ≥3	2,010 (37.9%)	780 (34.3 %)	165 (23.0 %)	651 (40.7%)	47 (46.1%)	366 (60.9%)
Not defined, No (%)	AIS missing	7 (0.2%)	(0.1%)	2 (0.3%)	1 (0.01%)		1(0.2%)
Pupils reactivity to light at admission, No (%)	Bilaterally reactive	4,402 (83.1%)	1,866 (81.9 %)	564 (78.8 %)	1,362 (85.1%)	94 (92.2%)	514 (85.5%)
	One pupil dilated unreactive	370 (7.0%)	177 (7.8%)	54 (7.5%)	115 (7.2%)	3 (2.9%)	20 (3.3%)
	Two pupils dilated unreactive	238 (4.5%)	128 (5.6%)	24 (3.3%)	62 (3.9%)	3 (2.9%)	(3.5%)
	Missing	290 (5.5%)	106 (4.7%)	74 (10.3 %)	62 (3.9%)	2 (2.0%)	46 (7.6%)
Pre-hospital GCS, No (%)	14-15	2,660 (50.2%)	1,054 (46.3 %)	360 (50.3 %)	812 (50.7%)	54 (52.9%)	379 (63.1%)
	9-13	971 (18.3%)	445 (19.5 %)	125 (17.5 %)	295 (18.4%)	7 (6.9%)	99 (16.5%)
	3-8	1,378 (26.0%)	725 (31.8 %)	163 (22.8 %)	394 (24.6%)	12 (11.8%)	84 (14.0%)
	Missing	291 (5.5%)	53 (2.3%)	68 (9.5%)	100 (6.2%)	29 (28.4%)	39 (6.5%)
Pre-hospital GCS, median (IQR)		14 ± 8	13 ± 8	14 ± 7	14 ± 7	15 ± 2	15 ± 3
Pre-hospital arterial pressure, No (%)	0-50 mmHg	79 (1.5%)	37 (1.6%)	6 (0.8%)	29 (1.8%)	1 (1.0%)	6 (1.0%)
	51-70 mmHg	228 (4.3%)	131 (5.7%)	16 (2.2%)	58 (3.6%)	1 (1.0%)	22 (3.7%)
	71-90 mmHg	689 (13.0%)	339 (14.9 %)	58.(8.1	197 (12.3%)	6 (5.9%)	89 (14.8%)
	>90 mmHg	3,780 (71.3%)	1,639 (72.0 %)	502 (70.1 %)	1,149 (71.8%)	59 (57.8%)	430 (71.6%)
	missing	524 (9.9%)	131 (5.7%)	134 (18.7	168 (10.5%)	35 (34.3%)	54 (9.0%)

Variable	Classification	Trauma System	TC level I (Hub) and direct admis sion	TC level I (Hub) and second ary referr al	Neurosu rgical TC level II (Spoke) and direct admissio n	Neurosu rgical TC level II (Spoke) and secondar y admissio n	Non- neurosur gical TC level II (Spoke)
				%)			
Pre-hospital hypoxia (SpO2<90%), No (%)		656 (12.4%)	267 (11.7 %)	45 (6.3%)	250 (15.6%)	29 (28.4%)	65 (10.8%)
30-day mortality, No (%)		825 (15.6%)	399 (17.5 %)	96 (13.4 %)	247 (15.4%)	13 (12.7%)	69 (11.5%)

Younger patients were more frequently admitted to Level I TCs and older patients to Level II TCs. Paediatric traumas were chiefly centralized at Level I TCs, particularly patients aged < 15 (91% between 0-2 years, 80% between 3-8, 76% between 9 and 11 years, and 60% aged 12 years and over). A slightly lower number of patients aged over 80 years were treated in Level I TCs (48% in Level I and 52% in Level II TCs).

Patients admitted to Level I TCs appeared less frequently to have comorbidities. A higher percentage of patients with GCS ≤ than 13 were admitted to Level I or neurosurgical Level II TCs.

Patient distribution according to three patterns of AIS values (reported in table 2).

Table 2

Patient distribution by type of SIAT in the period 2007-2012. Patients are described according to three patterns of AIS values. The reported data are restricted to the patients for whom AIS was available (5287 patients, 13 missing patients).

The sum of the percentages reported for all patients admitted to the Regional Trauma System. The percentages calculated in each column are given between square brackets.

Abbreviated Injury Score (AIS)¹⁹, Injury Severity Score (ISS)¹⁸, Trauma Center (TC). Traumatic Brain Injury (TBI),

		Trauma	a system v	without neuros	surgical	Trau	Trauma system with neurosurgical TC level II				
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Patients											
with											
ISS>15		1,472	1,083	200	393	3,815	1,905	1.700	200	321	
and full		(100%	(73.6	389	(36.3	(100%	(49.9	1,702	208	(16.8	
details in		()	%)	(26.4%)	%))	%)	(44.6%)	(5.4%)	%)	
AIS, No		,	. •)		,	,	. *)			. •)	
(%)											
TBI, No	AISc≥3	435	392	43	201	861	510	324	27	118	

(%)		(29.6 %)	(26.6 %)	(2.9%) [9.9%]	(51.3 %)	(22.6 %)	(13.4 %)	(8.5%) [37.6%]	(0.7%) [3.1%]	(23.1 %)
		[100%	[90.1 %]	[- · · · · ·]		[100%	[59.2 %]	[]	[27.7.1]	
Multiple injury, No (%)	AISc≥3 and AISmax ≥3	490 (33.3 %) [100%	391 (26.6 %) [79.8 %]	99 (6.7%) [20.2%]	124 (31.7 %)	1,493 (39.1 %) [100%	750 (19.7 %) [50.2 %]	680 (17.8%) [45.5%]	63 (1.7%) [4.2%]	106 (14.1 %)
Extracran ial injury, No (%)	AIS max extracran ial ≥3	547 (37.2 %) [100%	300 (20.4 %) [54.8 %]	247 (16.8%) [45.2%]	68 (26.7 %)	1,461 (38.3 %) [100%	645 (16.9 %) [44.1 %]	698 (18.3%) [47.8%]	118 (3.1%) [8.1%]	97 (15.0 %)

^{*:} referred to the Trauma Center

Direct admission to the Level I TC of Cesena (Hub of the Romagna, SIAT without a neurosurgical Level II TC)(1,083/1,472,73.6%) is higher than Level I TC of Emilia (SIAT with a neurosurgical Level II TC) (1,905/3815; 49.9%). In the SIATs without neurosurgical Level II TC, the latter is associated with a quite similar rate of direct admission to neurosurgical level II TC (1,702/3815, 44.6%).

Indirect admission was more frequent at the Level I TC of Cesena (Hub of the Romagna SIAT, in which no neurosurgical TC level II are included) (393/1083; 36.3% vs 321/1905; 16.8% at Level I TCs of Emilia). Roughly half of the patients with isolated TBI were indirectly admitted to the TC of Cesena (201/392; 51.3% vs 118/861; 23.1% at the Level I TCs of Emilia). Almost all indirect admissions to Level I TC of Cesena were referred from the non-neurosurgical Level II TCs in the Romagna SIAT (346/393; 88.0%)(Table 2). Conversely, the Level I TCs in Emilia SIAT indirectly admitted only a few patients from neurosurgical Level II TCs (39/321; 12.1%) (Table 3).

Table 3

Percentage of patients indirectly admitted to the dedicated trauma center by type of referring hospital, in the period 2007-2012.

The percentages calculated in each column are given between square brackets.

The reported data are restricted to the patients for whom AIS was available (5,287 patients, 13

missing patients). Abbreviated Injury Score (AIS)¹⁹, Injury Severity Score (ISS)¹⁸, Trauma Center (TC).

Traumatic Brain Injury (TBI),

	TC level I (Hub) in a SIAT without a neurosurgical TC level II (Spoke) Romagna					TC level I (Hub) in a SIAT with aTC level II (Spoke) Emilia					
Referr ed from	Tota 1					Tota 1	Non- neurosu rgical TC level II (Spoke)	neurosu rgical TC level II (Spoke)	Anot her TC level I (Hub	Anot her regio n	Miss ing

		nei	evel I (Hub) urosurgical Ro				TC level I (Hub) in a SIAT with aTC level II (Spoke) Emilia					
Referr ed from		Tota 1	Non- neurosu rgical TC level II (Spoke)	Anot her TC level I (Hub	Anot her regio n	Miss ing	Tota l	Non- neurosu rgical TC level II (Spoke)	neurosu rgical TC level II (Spoke)	Anot her TC level I (Hub	Anot her regio n	Miss ing
Total ISS>15 with second ary admissi on to trauma center, No (%)		393 (100 %)	346 (88.0%)	1 (0.3 %)	18 (4.6 %)	28 (7.1 %)	321 (100 %)	183 (57.0%)	39 (12.1%)	11 (3.4 %)	26 (8.1 %)	62 (19.4 %)
TBI, No (%)	AISc≥ 3	201 [51.1 %]	178 [45.3%]	1 [0.3 %]	8 [2.0 %]	14 [3.6 %]	118 [36.8 %]	83 [25.9%]	11 [3.4%]	1 [0.3 %]	4 [1.2 %]	19 [5.9 %]
Multipl e injury, No (%)	AISc≥ 3 and AISma x≥3	124 [31.6 %]	110 [28.0%]	0	5 [1.3 %]	9 [2.3 %]	106 [33.0 %]	63 [19.6%]	15 [4.7%]	6 [1.9 %]	7 [2.2 %]	15 [4.7 %]
Extracr anial injury, No (%)	AIS max extra cranial ≥3	68 [17.3 %]	58 [14.8%]	0	5 [1.3 %]	5 [1.3 %]	97 [30.2 %]	37 [11.5%]	13 [4.0%]	4 [1.2 %]	15 [4.7 %]	28 [8.7 %]

Discussion

Main results

The study shows that in Emilia Romagna over half of the patients with major trauma requiring ICU care were admitted to a designated Level I. This witness the adoption of the good scientific practice. Therefore, only 32.2% of the patients have direct access to neurosurgical level II TC.

The latter phenomena is not consistent in the three Trauma System. Even if theoretically the patients with isolated TBI should be admitted to Level I TCs, data has shown that they are intercepted by Level II TCs with neurosurgical facilities, even if these patients tend to be less severe. Furthermore, the percentage of patients with extracranial trauma in these centers is higher than in Level I TCs, but lower than in non-neurosurgical Level II TCs, suggesting a surrogate action of TC level I.

Congruently, in the Trauma System without neurosurgical Level II TCs, the rate of (35.1%) secondary referral to Level I TC for patients with TBI, either isolated or associated with multiple injuries, was substantially higher in respect to (9.5%) occurring in the Trauma Systems including

neurosurgical hospital. Otherwise the percentage of centralization in Romagna SIAT (35.1%) was similar to that in the UK (28.3%).[28]

This experience is probably more applicable to Europe than in Canadian or Australian regions, where population density is much lower, or in studies on regions of the USA, where exclusive trauma systems are usually headed by Level I TCs. However even in Italy, the results are not easy to compare with other data as neither the distinction between Level I and II TCs nor hub-and-spoke hierarchical systems are widespread and data set including AIS evaluation are not available. However, "the *National guidelines for defining standards of hospital care*" recently published in Italy advance the need to establish a network of functionally linked hospital facilities based on the integrated "hub and spoke" network model, which differentiates facilities by level of resource availability and expertise.[29]

Compared to the trauma model originally designed for the Emilia Romagna region, which envisaged Level II trauma centres as deputy for primary stabilization directly admitted of patients, the system seems instead to have been highly influenced by the presence of other hospitals with neurosurgical units. A study conducted by the same team,[30] based partly on RRTG data and partly on the ICD9-TMPM trauma severity score,[31] suggested benefits for younger and more severe patients admitted to Level I compared to Level II TCs, irrespective of the presence or absence of a neurosurgical facility.

What does the study add?

 The study therefore shows that a trauma system requires capacity and ability in healthcare provision. The system is based on the principle of centralization in high-volume centers (hubs) improve prognosis, but also encompasses other aspects, such as demographic and orographic characteristics, and local health service organization. Level II TCs are designated to provide primary patient stabilization and surgery for hemorrhagic patients, and to appropriately limit centralization of patients with numerous comorbidities. They also have a role in night-time centralization considering, for example, that helicopters are not permitted to fly during the hours of darkness. All these aspects justify the need for and role of spoke centers within the inclusive hub and spoke system. However, the availability of neurosurgery facilities is an important variable in final patient allocation, since it can reduce the volume of patients centralized in Level I TCs.

In the drawing of a trauma system it must be considered that the specific skills can affect the flow of patients over other operating factors such as the centralization protocols.

Conclusions

The study highlights that patient centralization is *per se* largely driven by the availability of neurosurgical facilities. Consequently, this factor is crucial for success of the Hub and Spoke

system. These considerations may be helpful in clinical governance for health systems planning to implement trauma systems.



Ethics Approval and Consent to Participate

The study was not submitted to the local Ethic Committee (Comitato Etico Unico di Ara Vasta Romagna, IRSST, Meldola, Italy) according its own indication (http://www.irst.emr.it/LIstituto/ReteOncologicaAreaVastaRomagna/ComitatoEticoUnicoIRS
http://www.irst.emr.it/LIstituto/ReteOncologicaAreaVastaRomagna/ComitatoEticoUnicoIRS
http://www.irst.emr.it/LIstituto/ReteOncologicaAreaVastaRomagna/ComitatoEticoUnicoIRS
https://www.irst.emr.it/LIstituto/ReteOncologicaAreaVastaRomagna/ComitatoEticoUnicoIRS
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https://www.irst.emr.it/Listituto/ReteOncologicaAreaVastaRomagna/ComitatoEticoUnicoIRS
https://www.garanteprivacy.it/web/guest). The data were fully anonymized and de-identified before analysis

Consent for publication

Not applicable

Funding

No funding. Data collection and analysis were done as a part of institutional activity of participants.

Conflict of Interest

I have read BioMed Central's guidance on competing interest and on behalf of all authors the corresponding author states that there is no conflict of interest

Data sharing statement

All data are stored in the server of the Assessorato per la Sanità della Regione Emilia Romagna, Via Aldo Moro 21, 40127 Bologna-. The data will not be shared because properties of the Regione Emilia Romagna health system. Extra data concerning patients severity and surgical intervention are available by emailing Rossana De Palma⁴, RDePalma@Regione.Emilia-Romagna.it,

Authors contribution

Arturo Chieregato and Rossanna De Palma: idea, planning data set, data analysis, wrote the manuscript

Annalisa Volpi², Giovanni Gordini³, planning data set, discussion of results, wrote the manuscript Chiara Ventura⁴, planning data set, data analysis, discussion of results

Marco Barozzi⁵, Maria Luisa Rita Caspani², Andrea Fabbri⁶, Anna Maria Ferrari⁷, Enrico Ferri⁸, Aimone Giugni³, Massimiliano Marino⁴, Costanza Martino⁹, Mario Pizzamiglio¹⁰, Maurizio Ravaldini⁹, Emanuele Russo⁹, Laura Trabucco⁷, Susanna Trombetti⁴, planning data set, discussion of results

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Tables

Table 1

Case material on 5300 patients in the period 2007-2012. Data on type of referral are limited to 5,293 patients (missing data on 7 patients concerning type of admission). AIS (Abbreviated Injury Score), ISS (Injury Severity Score), Trauma Center (TC).

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Table 2

Patient distribution by type of SIAT in the period 2007-2012. Patients are described according to three patterns of AIS values. The reported data are restricted to the patients for whom AIS was available (5,287 patients, 13 missing patients).

The sum of the percentages reported for all patients admitted to the Regional Trauma System. The percentages calculated in each column are given between square brackets.

AIS (Abbreviated Injury Score), ISS (Injury Severity Score), Trauma center (TC).

Table 3

Percentage of patients indirectly admitted to the dedicated trauma center by type of referring hospital, in the period 2007-2012.

The reported data are restricted to the patients for whom AIS was available (5,287 patients, 13 missing patients).

AIS (Abbreviated Injury Score), ISS (Injury Severity Score), Trauma center (TC).

Figures

Figure 1:

simplified map of the Emilia Romagna region. The territory is divided in the three Trauma Systems (SIATs) and the central location of the three correspondent Trauma Centers Level I (hubs) is reported. The population of each SIAT and every its district referring to Trauma Center Level II (spoke hospital) is described.

The location and the characteristics (neurosurgical versus not surgical) of the Trauma Centers level ted. II (spoke) is reported.

Appendix

Appendix Table 1

Trauma system organization and population distribution, average data per year from 2007 to 2013. Data Source http://statistica.regione.emilia-romagna.it/), Data are averaged overt the years and consequently the cumulative sums of partial does not fit with overall.

Appendix Table 2

Types of hospitals, * not in Cesena

Appendix Figure 1

Study case material

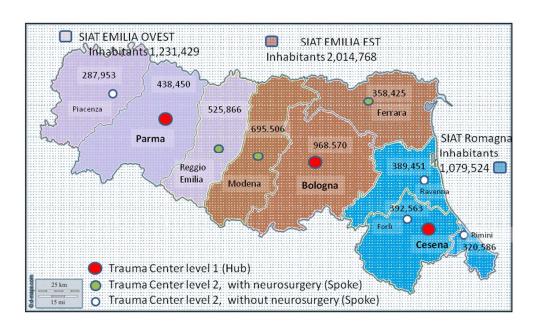


Figure 1: simplified map of the Emilia Romagna region. The territory is divided in the three Trauma Systems (SIATs) and the central location of the three correspondent Trauma Centers Level I (hubs) is reported. The population of each SIAT and every its district referring to Trauma Center Level II (spoke hospital) is described.

The location and the characteristics (neurosurgical versus not surgical) of the Trauma Centers level II (spoke) is reported.

254x190mm (96 x 96 DPI)

Appendix

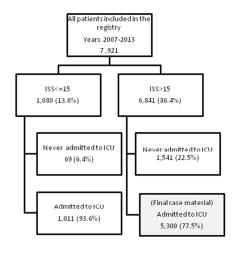
Table 1

Trauma system organization and population distribution, average data per year from 2007 to 2012. Data Source http://statistica.regione.emilia-romagna.it/), Data are averaged overt the years and consequently the cumulative sums of partial does not fit with overall.

	Population		Trauma centre (Hub)	Spoke				
Regione Emilia Romagna	4,333,088 (100%)		1,479,519 (34.1%)	2,853,568 (65.9%)				
				With neurosurgery (Trauma centre level II)	Without neurosurgery			
				1,560,889 (57.3%)	1,163,474 (42.7%)			
SIAT								
Emilia Ovest (Parma)			1 hospital	1 hospital	1 hospital			
	1,231,429		431,644	517,368 (41.9%)	284,763			
	(100%)		(29.2%)		(24.5%)			
			1 hospital	2 hospitals	0 hospital			
Emilia Est (Bologna,	2,014,768		845,046	1,043,521 (51.7%)	0			
Modena, Ferrara)	(100%)		(57.1%)					
			1 hospital	0 hospitals	6 hospitals			
Romagna	1,079,524		202,829	0	878,712			
	(100%)		(13.7%)		(75.5%)			

Table 2, Types of hospitals, * not in Cesena

	Level I trauma centres	Spoke hospital	
		With Neurosurgery (Level II trauma centre)	Without Neurosurgery
Hospitals	3	3	7
Trauma center level	I	П	III
Helicopter	At the hospital*, not night flight		
Emergency abdominal or thoracic surgery	24-hour ward	24-hour ward	24-hour ward
Cardiac surgery	24-hour ward*		
Neurosurgery	24-hour ward	24-hour ward	
Orthopedic surgery	24-hour ward*	24-hour ward	On call
Interventional radiology	On call	On call	
Transfusion service	On call	On call	On call
Maxillo-facial surgery	On call	On call	On call
Trauma service	yes	No	No
Coordination of the SIAT Trauma System	yes	No	No



254x190mm (96 x 96 DPI)

STROBE 2007 (v4) Statement—Checklist of items that should be included in reports of cross-sectional studies

Section/Topic	Item #	Recommendation	Reported on page #
Title and abstract	1	(a) Indicate the study's design with a commonly used term in the title or the abstract	1
		(b) Provide in the abstract an informative and balanced summary of what was done and what was found	2
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	3
Objectives	3	State specific objectives, including any prespecified hypotheses	4
Methods			
Study design	4	Present key elements of study design early in the paper	4
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	4-5
Participants	6	(a) Give the eligibility criteria, and the sources and methods of selection of participants	5
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe Not applicable comparability of assessment methods if there is more than one group	
Bias	9	Describe any efforts to address potential sources of bias	5
Study size	10	Explain how the study size was arrived at	Nor applcable
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	5 and 6
Statistical methods	12	(a) Describe all statistical methods, including those used to control for confounding	5
		(b) Describe any methods used to examine subgroups and interactions	5
		(c) Explain how missing data were addressed	Not applicable
		(d) If applicable, describe analytical methods taking account of sampling strategy	Not applicable
		(e) Describe any sensitivity analyses	Not applicable
Results			6

Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	6
		(b) Give reasons for non-participation at each stage	
		(c) Consider use of a flow diagram	Appendix, figure 1
Descriptive data 14	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	
		(b) Indicate number of participants with missing data for each variable of interest	
Outcome data	15*	Report numbers of outcome events or summary measures	Not applicable
Main results	16	(a) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	Page 6-11, table 1 to
		(b) Report category boundaries when continuous variables were categorized	Page 6-11, table 1 to 3
		(c) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	Not applicable
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	Not applicable
Discussion			
Key results	18	Summarise key results with reference to study objectives	11
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	12
Generalisability	21	Discuss the generalisability (external validity) of the study results	12
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	13

^{*}Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at www.strobe-statement.org.

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How health service delivery guides the allocation of major trauma patients in the intensive care units of the inclusive (Hub & Spoke) trauma system of the Emilia Romagna Region (Italy). A cross sectional study

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SCP M.

How health service delivery guides the allocation of major trauma patients in the intensive care units of the inclusive (Hub & Spoke) trauma system of the Emilia Romagna Region (Italy). A cross sectional study

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Abstract

<u>Objective</u>: To evaluate cross-sectional patient distribution and standardized 30-day mortality in the intensive care units (ICU) of an inclusive hub and spoke trauma system.

<u>Setting</u>: ICUs of the Trauma System (SIAT) of Emilia-Romagna, an Italian region with a population of approximately 4.5 million.

<u>Participants</u>: 5,300 patients with an Injury Severity Score (ISS) >15, were admitted to the regional ICUs and recorded in the Regional Severe Trauma Registry, between 2007 and 2012. Patients were classified by the Abbreviated Injury Score as follow a) traumatic brain injury, b) multiple injuries, c) extracranial lesions. The SIATs were divided into those with at least one neurosurgical Level II trauma centre (TC) and those with a neurosurgical unit in the Level I TC only.

Results:

A higher proportion of patients (out of all SIAT patients) were admitted to the Level I TC at the head of the SIAT with no additional neurosurgical facilities (1083/1472, 73.6%) compared to the Level I TCs heading SIATs with neurosurgical Level II TCs (1905/3815; 49.9%). A similar percentage of patients were admitted to Level I TCs (1905/3815; 49.9%) and neurosurgical Level II TCs (1702/3815, 44.6%) in the SIATs with neurosurgical Level II TCs. Observed versus expected mortality (OE) was not statistically different among the three types of centre with a neurosurgical unit, however the best mean OE values were observed in the Level I TC in the SIAT with no neurosurgical unit.

<u>Conclusion:</u> The Hub and Spoke concept was fully applied in the SIAT in which neurosurgical facilities were available in the Level I TC only. The performance of this system suggests that competition among Level I and Level II TCs in the same Trauma System reduces performance in both. The density of neurosurgical centres must be considered by public health system governors before implementing Trauma Systems.

Article summary.

Strengths and limitations of this study

The study is based on a seven-year institutional prospective cross-sectional data collection, including 30-day mortality data, relating to an entire Italian Region. Although the data were gathered in a specific Italian region with a well-established public health system, they are potentially generalizable to other densely populated countries with a predominance of publicly delivered healthcare services.

The association between a higher number of neurosurgical centres and greater competition in patient allocation must be considered with caution because several potential sources of differences among SIATs and TCs were not recorded

Considering the highly selected setting and similarities in the basic standard of care among centres, a larger sample is probably needed to detect any minor differences in outcome related to final trauma patient allocation.

Background

Trauma is a major issue for society and a challenge for health policy makers. In Italy it is chiefly associated with road accidents [1-4] Regionalized trauma systems have been designed in many countries to provide a coordinated, organized response to injury [5] Concentrating patients in a few Level I trauma centres (TC) to ensure prompt, specialized care should improve patient outcomes.[5] Health authorities in several countries have used guidelines to designate hospitals as Level I to IV TCs.[6] There is a general consensus that Level I TCs should admit at least 200 patients with major trauma per year.[5,7]

Currently most regional trauma systems in the United States are based on the "exclusive" design,-but this prevents non-TC acute care facilities from participating in the treatment of less severe trauma patients, with the risk of expertise at non-TCs falling below critical levels. By contrast Europe - which is more urbanized and has a higher density of hospitals - more frequently adopts an "inclusive" model, encompassing non-TC hospitals (spoke centers) that care chiefly for less severe trauma [8]. In this system, Level 1 TCs (hubs) are central to trauma system organization [8]. They directly admit the patients who appear most severe at the scene and indirectly receive those who are undertriaged at first admission or who deteriorate after admission to a spoke centre.

In 2002, the regional health service of Emilia Romagna, in the north of Italy, designed three trauma systems, headed by three Level I TCs, based on geographic location, previous organizational history, and presence of clinical expertise (DGR 1267/2002)[9-10]. The organizations are referred to as "Sistema Integrato Assistenza Traumi (SIAT: Integrated System for Trauma Patient Care)", each representing a separate, specific Trauma System. In addition to a Level I TC, two of these SIATs also included Level II TCs with neurosurgical units. Considering the importance of traumatic brain injury (TBI) in trauma patients, it could be that these neurosurgical units centralize patients who would otherwise have been admitted to Level I TCs.

The aim of this study was to describe access to intensive care by major trauma patients, within the various SIATs, ten years after establishment of Emilia Romagna's Integrated System, and to discuss whether the availability of neurosurgical facilities may had influenced this process.

Material and Methods

<u>Setting:</u> Emilia-Romagna is an Italian region with a population of approximately 4.5 million (Figure 1 and online supplement Appendix Table 1) [11].

 The "inclusive" model of trauma care included community and teaching hospitals not dedicated exclusively to trauma. All were linked to a dedicated Emergency Medical Service, including a helicopter. The SIAT characteristics are described in the Appendix (Appendix Table 2)[6]. The underlying philosophy of the inclusive hub and spoke trauma system is that Level I TCs function as hubs within highly specialized hospitals and other Level II TC facilities serve as "spokes". Some Level II TCs have neurosurgical units. The SIATs differ from each other in that one of them has no neurosurgical Level II unit (Romagna) while neurosurgical units are present in the other two.

In summary, the Trauma System is organized according to:

- a) three subtypes of centre:
- Level I TCs: Bologna Maggiore, Parma, Cesena hospitals
- Level II TCs with neurosurgery: Modena Baggiovara, Ferrara, Reggio Emilia hospitals
- Level II TCs with no neurosurgery: Rimini, Riccione, Forlì, Ravenna, Faenza, Lugo, Piacenza
 - b) two subtypes of SIAT:
- SIAT with a neurosurgical Level II TC;
- SIAT with no neurosurgical Level II TC.

The system embraces the concept of back transferring patients from the hub to the spoke, once they have been stabilized and specialist problems have been solved [12]. The ICU network is further supported by a network of rehabilitation units [13].

The protocols to describe direct access from the scene to the Level I TC and secondary referral from Level II TCs were drawn up in each of three Trauma Systems. However, Romagna has been implementing telemedicine for TBI since the 1990s [14-15].

Since 2007, data on the severity of patient admissions in the Emilia Romagna region have been prospectively collected by the three Level I TCs and ten other spoke hospitals in the regional severe trauma registry (Registro Regionale Traumi Gravi, RRTG) [16,17]. The system has been regularly monitored by a commission which checks data and implements system organization [18].

Case material

The cross-sectional study was conducted using data from the RRTG. The case material analysed for the study consisted of consecutive cases collected from 2007 to 2012 (Appendix Figure 1). The criteria for inclusion in the registry was traumatic injury with an Injury Severity Score (ISS) greater than 15 or admission to an intensive care unit (ICU) [19-20]. Consequently, a potential source of bias is that patients admitted to the regular ward were not considered in the study. Injury severity was coded according to the Abbreviated Injury Score 1990 (AIS) (1998 update), by a trained coder at each

hospital. Training was self-managed by the regional authorities, with no official certification by the Association for the Advancement of Automotive Medicine.

Descriptive analysis of patient distribution

 Patients can be transferred from one hospital to another within the trauma system but are recorded in the registry only once. The following attribution criteria were applied for registry entries: a) the first admitting hospital, b) the data recorded in the ward providing the most intensive therapy, in the said hospital.

Patients were also classified in three categories by type of anatomical lesion. The objective was to identify patients with clinically relevant extracranial injuries, those with clinically relevant cranial or spinal injuries, and those with both clinically relevant extracranial or cranial/spinal injuries.

We used an a priori AIS cutoff of <3 and ≥3 to classify relevant or non-clinical lesions, respectively. An AIS cranial score ≥3 was used to classify moderate or severe TBI [21-24], although this differs from the conventional classification [25-26].

Accordingly, the patients were classified as follows:

- patients with <u>moderate or severe TBI and/or cervical spine injury</u>: with an AIS cranial score value ≥3 and an AIS extracranial score;
- patients with <u>severe multiple injuries including TBI and/or cervical spine injury</u>: with extracranial and cranial lesions, both with AIS score ≥ 3;
- patients with <u>extracranial lesions</u>: with at least one extracranial AIS score of ≥ 3 and a cranial AIS of ≤ 3 .

Patients' clinical severity was also described by the ISS, by the AIS and the Glasgow Coma Scale (GCS) [25]. Comorbidities were assessed by the Charlson Score Index [27].

The data were analyzed descriptively. Continuous variables were expressed as mean, standard deviation, median and range. Age was described both as a continuous value and in three categories according to cut-off ages of 20 and 70 years.

Standardized mortality

Thirty-day patient mortality was standardized according to several covariates using a hierarchical logistic regression model. This has already been published by our group [28]. The model included the following covariates: age (continuous variable), ISS (continuous variable), gender (continuous variable), mechanism of injury (traffic accident, fall, penetrating, other, missing or unknown), motor

GCS (continuous variable), systolic blood pressure (0-49 mmHg, 50-89 mmHg, 90-179 mmHg, ≥180 mmHg). Taking the sum of observed deaths and the sum of the individual probability of death (from 0 to 1, obtained by solving the logistic equation), we determined the Observed/Expected ratio (OE)[29]. The OE was calculated separately for patients with moderate or severe TBI or cervical spine injury and patients with severe multiple injuries, and was compared among a) Level I TC in SIATs without a neurosurgical Level I TC (Cesena hospital), b) Level I TCs in SIATs with neurosurgical spokes (Bologna Maggiore and Parma hospitals) and c) neurosurgical Level II TCs (Modena Baggiovara, Ferrara, Reggio Emilia hospitals).

All analyses were carried out with the SAS 8.2 System (SAS Institute, North Carolina). The study was conducted in adherence to regional privacy regulation No.3 of Emilia-Romagna dated 24 April 2006 (Title: Sensitive data processing) and act N.1 of 30 May 2014, which was still in force at the time of writing. In addition, each patient had an anonymous identifier assigned by the Regione Emilia Romagna to enable each individual to be tracked over time without jeopardizing patient privacy.

Results

After applying the inclusion criteria, 5,300 patients were eligible for the study. However, details on the AIS categories were available for only 5,287 patients.

General and specific characteristics of patients (reported in Table 1).

Table 1:_Case material on 5,300 patients in the period 2007-2012. Data on type of referral are limited to 5,293 patients (missing data on 7 patients concern type of admission). Comorbidities were assessed by the Charlson Score Index²⁷, Abbreviated Injury Score (AIS)²⁰, Glasgow Coma Scale (GCS)²⁵, Injury Severity Score (ISS)¹⁹, Trauma Centre (TC). Traumatic Brain Injury (TBI)

Variable	Classification	Trauma System	TC level I (Hub) and direct admis sion	TC level I (Hub) and second ary referr al	Neuro surgical TC level II (Spoke) and direct admissio n	Neuro surgical TC level II (Spoke) and secondar y admissio n	Non- neuro surgical TC level II (Spoke)
No.		5300	*2,274 (43- 1%)	*716 (13.5 %)	*1,600 (30.2%)	*102 (1.9%)	**600 (11.3%)
Age, Median (IQR)		46 ± 38	44 ± 38	48 ± 39	47 ± 37	$56,5 \pm 39$	49 ± 41
Gender , No (%)	male	3,905 (73.7%)	1,720 (75.5	512 (71.5	1,182 (73.8%)	68 (66.7%)	421 (70.1%)

Variable	Classification	Trauma System	TC level I (Hub) and direct admis sion	TC level I (Hub) and second ary referr al	Neuro surgical TC level II (Spoke) and direct admissio n	Neuro surgical TC level II (Spoke) and secondar y admissio n	Non- neuro surgical TC level II (Spoke)
			%)	%)			
Type of trauma, No (%)	Closed	5,160 (97.4%)	2,222 (97.6 %)	695 (97.1 %)	1,573 (95.3%)	100 (98.0%)	567 (94.3%)
	Penetrating	113 (2.1%)	50 (2.2%)	15 (2.1%)	28 (1.7%)	2 (2.0%)	18 (3.0%)
	Missing	27 (0.5%)	5 (0.2%)	6 (0.8%)	-	-	16 (2.7%)
Mechanism of injury, No (%)	Traffic	3,517 (66.4%)	1,561 (68.6 %)	370 (51.7 %)	1,107 (69.1%)	50 (49.0%)	427 (71.1%)
	Minor Fall	1,112 (21.0%)	454 (19.9 %)	219 (30.6 %)	324 (20.2%)	37 (36.3%)	77 (12.8%)
	Major fall	153 (2.9%)	59 (2.6%)	18 (2.5%)	65 (4.1%)	2 (2.0%)	9 (1.5%)
	Crush	129 (2.4%)	54 (2.4%)	15 (2.1%)	34 (2.1%)	1 (1.0%)	25 (4.2%)
	Other	361 (6.8%)	145 (6.4%)	89 (12.4 %)	70 (4.4%)	12 (11.8%)	45 (7.5%)
	Missing	28 (0.5%)	4 (0.2%)	5 (0.7%)	1 (0.1%)	-	18 (3.0%)
Charlson Comorbidity Index ²⁸ , No (%)	0	4,595 (86.7%)	2,035 (89.4 %)	619 (86.5 %)	1,351 (84.4%)	85 (83.3%)	502 (85.5%)
	1	317 (6.0%)	102 (4.5%)	52 (7.3%)	101 (6.3%)	8 (7.8%)	54 (9.0%)
	≥2	388 (7.3%)	140 (6.2%)	45 (6.3%)	149 (9.3%)	9 (8.8%)	45 (7.5%)
ISS ¹⁹ , median (IQR)		26 ± 12	26 ± 12	25 ± 12	27 ± 13	25 ± 11	25 ± 14
TBI, No (%)	AISc≥3	1,298 (24.5%)	583 (25.6 %)	319 (44.6 %)	299 (18.7%)	25 (24.5%)	70 (11.6%)
Multiple injury, No (%)	AISc≥3 and AISmax≥3 ²⁰	1,985 (37.4%)	911 (40.0 %)	230 (32.1 %)	650 (40.6%)	30 (39.4%)	164 (27.3%)
Extracranial injury, No (%)	AIS max extracranial ≥3 ²⁰	2,010 (37.9%)	780 (34.3 %)	165 (23.0 %)	651 (40.7%)	47 (46.1%)	366 (60.9%)
Not defined, No (%)	AIS missing ²⁰	7 (0.2%)	3 (0.1%)	2 (0.3%)	1 (0.01%)		1(0.2%)
Pupil reactivity to light at admission, No (%)	Bilaterally reactive	4,402 (83.1%)	1,866 (81.9	564 (78.8	1,362 (85.1%)	94 (92.2%)	514 (85.5%)

Variable	Classification	Trauma System	TC level I (Hub) and direct admis sion	TC level I (Hub) and second ary referr al	Neuro surgical TC level II (Spoke) and direct admissio n	Neuro surgical TC level II (Spoke) and secondar y admissio n	Non- neuro surgical TC level II (Spoke)
			%)	%)			
	One pupil dilated unreactive	370 (7.0%)	177 (7.8%)	54 (7.5%)	115 (7.2%)	3 (2.9%)	20 (3.3%)
	Two pupils dilated unreactive	238 (4.5%)	128 (5.6%)	24 (3.3%)	62 (3.9%)	3 (2.9%)	21 (3.5%)
· ·	Missing	290 (5.5%)	106 (4.7%)	74 (10.3 %)	62 (3.9%)	2 (2.0%)	46 (7.6%)
Pre-hospital GCS ²⁵ , No (%)	14-15	2,660 (50.2%)	1,054 (46.3 %)	360 (50.3 %)	812 (50.7%)	54 (52.9%)	379 (63.1%)
	9-13	971 (18.3%)	445 (19.5 %)	125 (17.5 %)	295 (18.4%)	7 (6.9%)	99 (16.5%)
	3-8	1,378 (26.0%)	725 (31.8 %)	163 (22.8 %)	394 (24.6%)	12 (11.8%)	84 (14.0%)
	Missing	291 (5.5%)	53 (2.3%)	68 (9.5%)	100 (6.2%)	29 (28.4%)	39 (6.5%)
Pre-hospital arterial pressure, No (%)	0-50 mmHg	79 (1.5%)	37 (1.6%)	6 (0.8%)	29 (1.8%)	1 (1.0%)	6 (1.0%)
	51-70 mmHg	228 (4.3%)	131 (5.7%)	16 (2.2%)	58 (3.6%)	1 (1.0%)	22 (3.7%)
	71-90 mmHg	689 (13.0%)	339 (14.9 %)	58.(8.1 %)	197 (12.3%)	6 (5.9%)	89 (14.8%)
	>90 mmHg	3,780 (71.3%)	1,639 (72.0 %)	502 (70.1 %)	1,149 (71.8%)	59 (57.8%)	430 (71.6%)
	missing	524 (9.9%)	131 (5.7%)	134 (18.7 %)	168 (10.5%)	35 (34.3%)	54 (9.0%)
Pre-hospital hypoxia (SpO2<90%), No (%)		656 (12.4%)	267 (11.7 %)	45 (6.3%)	250 (15.6%)	29 (28.4%)	65 (10.8%)
30-day mortality, No (%)		825 (15.6%)	399 (17.5 %)	96 (13.4 %)	247 (15.4%)	13 (12.7%)	69 (11.5%)

Younger patients were more frequently admitted to Level I TCs and older patients to Level II TCs. Paediatric traumas were chiefly centralised at Level I TCs, particularly patients aged <15 (in 91% of cases between 0-2 years, 80% between 3-8, 76% between 9 and 11 years, and 60% aged 12 years and

over). A slightly lower number of patients aged over 80 years were treated in Level I TCs (48% in Level I and 52% in Level II TCs). This observation is more clearly summarised in Figure 2.

Patients admitted to Level I TCs less frequently appeared to have comorbidities. A higher percentage of patients with GCS ≤13 were admitted to Level I or neurosurgical Level II TCs.

<u>Patient distribution according to three patterns of AIS values</u> (reported in Table 2).

Table 2

Patient distribution by type of SIAT in the period 2007-2012. Patients are described according to three patterns of AIS values. The reported data are restricted to the patients for whom AIS was available (5,287 patients; 13 missing patients).

The sum of the percentages reported for all patients admitted to the Regional Trauma System. The percentages calculated in each column are given between square brackets.

Abbreviated Injury Score (AIS)²⁰, Injury Severity Score (ISS)¹⁹, Trauma Centre (TC). Traumatic Brain Injury (TBI)

			stem withou kes (Romag	t neurosurgica gna)	ıl TC	Trauma system with neurosurgical TC level II spokes (Emilia)					
			TC level I (Hub)	Non- neuro- surgical TC level II (Spoke)	Indire ct access to the TC level I*		TC level I (Hub)	Neuro- surgical TC level II (Spoke)	Non- neuro- surgical TC level II (Spoke)	Indirect access to the TC level I*	
Patients with ISS ¹⁹ >15 and full details in AIS, No (%)		1,472 (100%)	1,083 (73.6%)	389 (26.4%)	393 (36.3 %)	3,815 (100%)	1,905 (49.9 %)	1,702 (44.6%)	208 (5.4%)	321 (16.8%)	
TBI, No (%)	AISc≥3	435 (29.6%) [100%]	392 (26.6%) [90.1%]	43 (2.9%) [9.9%]	201 (51.3 %)	861 (22.6%) [100%]	510 (13.4 %) [59.2 %]	324 (8.5%) [37.6%]	27 (0.7%) [3.1%]	118 (23.1%)	
Multiple injury, No (%)	AISc≥3 and AISmax ≥3 ²⁰	490 (33.3%) [100%]	391 (26.6%) [79.8%]	99 (6.7%) [20.2%]	124 (31.7 %)	1,493 (39.1%) [100%]	750 (19.7 %) [50.2 %]	680 (17.8%) [45.5%]	63 (1.7%) [4.2%]	106 (14.1%)	
Extra- cranial injury, No (%)	AIS max extra cranial ≥3 ²⁰	547 (37.2%) [100%]	300 (20.4%) [54.8%]	247 (16.8%) [45.2%]	68 (26.7 %)	1,461 (38.3%) [100%]	645 (16.9 %) [44.1 %]	698 (18.3%) [47.8%]	118 (3.1%) [8.1%]	97 (15.0%)	

^{*:} referred to the Trauma Centre

A higher proportion of all trauma system patients were admitted directly to the Level I TC of Cesena (Hub of the Romagna SIAT with no neurosurgical Level II TC) (1,083/1,472; 73.6%) compared to the Level I TCs of Emilia with neurosurgical Level II TCs (1,905/3815; 49.9%). In the SIAT of Emilia with no neurosurgical Level II TC, the proportion of all trauma system patients directly admitted to the Level I TCs (Bologna Maggiore and Parma) was a relatively similar to the percentage of direct admissions to neurosurgical Level II TCs (1,702/3815, 44.6%).

Indirect admission was more frequent at the Level I TC of Cesena (Hub of the Romagna SIAT, with no neurosurgical TC level II) (393/1083; 36.3% vs 321/1905; 16.8% at Level I TCs of Emilia). Roughly half of the patients with isolated TBI were indirectly admitted to the TC of Cesena (201/392; 51.3% vs 118/861; 23.1% at the Level I TCs of Emilia). In the SIAT of Romagna almost all indirect admissions to Level I TC of Cesena were referred from non-neurosurgical Level II TCs (346/393; 88.0%) (Table 2). Conversely, the Level I TCs in the Emilia SIAT indirectly admitted only a few patients from neurosurgical Level II TCs (39/321; 12.1%) (Table 3).

Table 3 Percentage of patients indirectly admitted to the dedicated trauma centre by type of referring hospital, in the period 2007-2012.

The percentages calculated in each column are given between square brackets.

The reported data are restricted to the patients for whom AIS was available (5,287 patients, 13 missing patients). Abbreviated Injury Score (AIS)²⁰, Injury Severity Score (ISS)¹⁹, Trauma Centre (TC). Traumatic Brain Injury (TBI)

		neu	evel I (Hub rosurgical R	,	el II (Sp		TC level I (Hub) in a SIAT with aTC level II (Spoke Emilia						
Referred from		Total	Non- neuro- surgica 1 TC level II (Spoke)	Anot her TC level I (Hub	Anot her regio n	Missi ng	Total	Non- neuro- surgical TC level II (Spoke)	Neuro- surgical TC level II (Spoke)	Anot her TC level I (Hub	Anot her regio n	Miss ing	
Total ISS ¹⁹ >15 with secondary admission to trauma centre, No (%)		393 (100 %)	346 (88.0%)	1 (0.3 %)	18 (4.6 %)	28 (7.1%)	321 (100%)	183 (57.0%)	39 (12.1%)	11 (3.4 %)	26 (8.1 %)	62 (19.4 %)	
TBI, No (%)	AIS c≥3 ₂₀	201 [51.1 %] 124	178 [45.3%]	1 [0.3 %]	8 [2.0 %]	14 [3.6%]	118 [36.8 %] 106	83 [25.9%]	11 [3.4%]	1 [0.3 %]	4 [1.2 %]	19 [5.9 %]	

			TC level I (Hub) in a SIAT without a neurosurgical TC level II (Spoke) Romagna					TC level I (Hub) in a SIAT with aTC level II (Spoke Emilia						
Referred from		Total	Non- neuro- surgica 1 TC level II (Spoke)	Anot her TC level I (Hub	Anot her regio n	Missi ng	Total	Non- neuro- surgical TC level II (Spoke)	Neuro- surgical TC level II (Spoke)	Anot her TC level I (Hub	Anot her regio n	Miss ing		
injury, No (%)	c≥3 and AIS max ≥3 20	[31.6 %]	[28.0%]		[1.3 %]	[2.3%]	[33.0 %]	[19.6%]	[4.7%]	[1.9 %]	[2.2 %]	[4.7 %]		
Extra- cranial injury, No (%)	AIS max extr a cran ial ≥3 20	68 [17.3 %]	58 [14.8%]	0	5 [1.3 %]	5 [1.3%]	97 [30.2 %]	37 [11.5%]	13 [4.0%]	4 [1.2 %]	15 [4.7 %]	28 [8.7 %]		

Standardized mortality

Observed versus expected mortality (OE) at 30 days was not statistically different among the three types of centre with a neurosurgical unit (Figure 3). However, the graphs show the progressive improvement in the mean OE value moving from neurosurgical level II TCs (Modena Baggiovara, Ferrara, Reggio Emilia hospitals) to the Level I TCs in SIATs with additional neurosurgical units (Bologna Maggiore, Parma) and, finally, to the only Level I TC in a SIAT with no neurosurgical unit (Cesena).

Discussion

Main results

The study shows that in Emilia Romagna over half of the patients with major trauma requiring ICU care were admitted to a designated Level I centre. This is testament to the adoption of good scientific practice. Only 32.2% of the patients were admitted directly to a neurosurgical level II TC.

The above phenomena is not consistent in the three Trauma Systems. While patients with isolated TBI should theoretically be admitted to Level I TCs, data have shown that they are intercepted by Level II TCs with neurosurgical facilities, even though they tend to be less severe. Furthermore, the percentage

 of patients with extracranial trauma in these centres is higher than in Level I TCs, but lower than in non-neurosurgical Level II TCs, suggesting that Level I TCs act as a surrogate.

Fittingly, the rate of secondary referral to a Level I TC for patients with TBI, be it isolated or associated with multiple injuries, was substantially higher in the SIAT with no neurosurgical Level II TCs (35.1%) than in the SIATs with a neurosurgical facility (9.5%). The rate of centralization in the Romagna SIAT (35.1%) was similar to in the UK rates (28.3%) [30].

The experience described in the study probably applies more to Europe than to Canadian or Australian regions, where population density is much lower, or to the USA, where exclusive trauma systems are usually headed by Level I TCs. Even in Italy the results are not easy to compare with other national data as neither the distinction between Level I and II TCs nor hub-and-spoke hierarchical systems are widely adopted and no other data sets including AIS evaluation are available. The "National guidelines for defining standards of hospital care", recently published in Italy, do however stress the need to establish a network of functionally linked hospital facilities based on the integrated "hub and spoke" network model, which differentiates facilities by level of resource availability and expertise [31].

Compared to the trauma model originally designed for the Emilia Romagna region, in which Level II trauma centres were entrusted with primary stabilisation of directly admitted patients, the system seems instead to have been highly influenced by the presence of other hospitals with neurosurgical units. A study conducted by the same team [32], based partly on RRTG data and partly on the ICD9-TMPM trauma severity score [28], suggested that younger and more severe patients benefited from admission to Level I compared to Level II TCs, irrespective of the presence or absence of a neurosurgical unit.

The study does not adequately answer the question whether such patient allocation affects patient outcome since the wide confidence interval precludes any statistical significance. Nevertheless, the Observed to Expected mortality data standardised by patient severity suggest that competition among Level I and Level II TCs in the same Trauma System reduces performance in both. Mean performance values suggest that the Level I TC working without competition from a neurosurgical Level II TC performs better. Similarly, the neurosurgical level II TC competing with the Level I TC in same SIAT, seems to have the worst OE. Data seem to indicate that lower competition among centres leads to more volume in Level I TC and consequently to more expertise.

What does the study add?

The study shows that a trauma system requires capacity and ability in healthcare provision. The Trauma System, based on the principle of centralization in high-volume centres (hubs), improves prognosis, but

also takes account of other aspects, as demographic and orographic characteristics, and local health service organization. Level II TCs are designated to provide primary patient stabilisation and surgery for haemorrhagic patients, and to appropriately limit centralization of patients with numerous comorbidities. They also have a role in night-time centralization considering, for example, that helicopters are not permitted to fly during the hours of darkness. All these aspects justify the need for spoke centres within the inclusive hub and spoke system. The availability of neurosurgery facilities remains an important variable in final patient allocation, since it can help reduce the volume of patients centralised in Level ITCs.

Development of a Trauma System must considered the specific skills that can affect patient flow over other operating factors such as the centralization protocols.

Limitations

 The study did not evaluate patient-allocation factors associated with rural versus highly urbanized areas, orography, night-time restrictions, or individual hospital resources, which can affect supply and demand. No assessment was made of local history, habitual practice prior to implementation of the Trauma System, or differences in the scope of the auditing process in each Trauma System with regard to centralization. As a result, the study does not explore in depth why the centralization rate varied in the different Trauma Systems in the same regional organization. The association between a higher number of neurosurgical centres and greater patient dispersion cannot therefore be considered a definitive causation. Furthermore, the study results probably also suffer from the lack of inclusion of patients with ISS>15 admitted to a regular ward.

The study applies to the region of Emilia Romagna. Within the Italian National Health System, healthcare is autonomously planned at the regional level, thus limiting the generalizability of the results. However, since numerous Italian regions have similar orographic and healthcare characteristics to those of Emilia Romagna, and several regions have numerous neurosurgical centres, this report could be of some help to those planning to develop Trauma Systems. Finally, considering the highly-selected territory analyzed, and the spread of standards of care, the sample size is probably not yet appropriate to observe differences in performance among different subtypes of centre.

Lastly, any evaluation of patient distribution should be corroborated by an analysis linking clinical governance to an outcome. In the present study, 30-day mortality was collected and standardized, with findings suggesting that competition among centres does not help improve patient outcomes. The general limitations, and the strengths, of the use of standardized OE to compare Trauma Centre

performance has been appropriately described by Shafi [29]. In the present, highly selected setting, the similar basic standard of care among centres probably need a more extensive sample size to detect small potential differences in outcome associated with the final allocation of different trauma patients. Conversely, waiting to collect several years of data before adjusting system organization would not be cost effective. Hence, by associating the data with qualitative system evaluation and expert opinion, the findings - while not statistically significant - could be sufficiently meaningful to anyone appointed to oversee clinical governance of a Trauma System.

Conclusions

The study highlights that patient centralization is *per se* largely driven by the availability of neurosurgical facilities. Consequently, this factor is crucial to the success of the Hub and Spoke system. These considerations may be helpful in the clinical governance of health systems planning to implement Trauma Systems.

Ethics Approval and Consent to Participate

The study was not submitted to the local Ethics Committee (Comitato Etico Unico di Area Vasta IRSST, Romagna, Meldola, Italy), in accordance with its indications own (http://www.irst.emr.it/LIstituto/ReteOncologicaAreaVastaRomagna/ComitatoEticoUnicoIRSTA VR/tabid/2363/Default.aspx). The study was observational and retrospective and was conducted on data collected according to the indications of the Italian regulatory board (Garante per la protezione dei dati personali: http://www.garanteprivacy.it/web/guest). The data were fully anonymised and de-identified before analysis

Consent for publication

Not applicable

Funding

No funding. Data collection and analysis were done as a part of ongoing institutional activities.

Competing interests

None

Data sharing statement

All data are stored in the server of the Assessorato per la Sanità della Regione Emilia Romagna, Via Aldo Moro 21, 40127 Bologna-. The data will not be shared because they are the property of the Regione Emilia Romagna health system. Extra data concerning patient severity and surgical intervention are available from Rossana De Palma⁴, by emailing RDePalma@Regione.Emilia-Romagna.it,

Authors contribution

Arturo Chieregato and Rossana De Palma: idea, planning data set, data analysis, wrote the manuscript Annalisa Volpi², Giovanni Gordini³, planning data set, discussion of results, wrote the manuscript Chiara Ventura⁴, planning data set, data analysis, discussion of results

Marco Barozzi⁵, Maria Luisa Rita Caspani², Andrea Fabbri⁶, Anna Maria Ferrari⁷, Enrico Ferri⁸,

Aimone Giugni³, Massimiliano Marino⁴, Costanza Martino⁹, Mario Pizzamiglio¹⁰, Maurizio Ravaldini⁹,

Emanuele Russo⁹, Laura Trabucco⁷, Susanna Trombetti⁴, planning data set, discussion of results

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- 6. HYPERLINK

"http://www.amtrauma.org/?page=TraumaLevels"http://www.amtrauma.org/?page=TraumaLevel

7. HYPERLINK

- "http://www.gazzettaufficiale.it/eli/id/2015/06/04/15G00084/sg"http://www.gazzettaufficiale.i t/eli/id/2015/06/04/15G00084/sg DECRETO 2 aprile 2015, n. 70 Regolamento recante definizione degli standard qualitativi, strutturali, tecnologici e quantitativi relativi all'assistenza ospedaliera. (15G00084) (GU n.127 del 4-6-2015)
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Tables

Table 1

Case material on 5,300 patients in the period 2007-2012. Data on type of referral are limited to 5,293 patients (missing data on 7 patients concerning type of admission). AIS (Abbreviated Injury Score), ISS (Injury Severity Score), Trauma Centre (TC).

Table 2

Patient distribution by type of SIAT in the period 2007-2012. Patients are described according to three patterns of AIS values. The reported data are restricted to the patients for whom AIS was available (5,287 patients, 13 missing patients).

The sum of the percentages reported for all patients admitted to the Regional Trauma System. The percentages calculated in each column are given between square brackets.

AIS (Abbreviated Injury Score), ISS (Injury Severity Score), Trauma Centre (TC).

Table 3

Percentage of patients indirectly admitted to the dedicated trauma centre by type of referring hospital, in the period 2007-2012.

The reported data are restricted to the patients for whom AIS was available (5,287 patients, 13 missing patients).

AIS (Abbreviated Injury Score), ISS (Injury Severity Score), Trauma Centre (TC).

Figures

Figure 1:

Simplified map of the Emilia Romagna region. The territory is divided into three Trauma Systems (SIATs) and the central location of the three corresponding Trauma Centres Level I (hubs) is reported. The population of each SIAT and each district referring to the Level II Trauma Centre (spoke hospital) are described.

The location and characteristics (neurosurgical versus not surgical) of the Level II Trauma Centres (spoke) are reported.

Figure 2:

Patients distribution according to age into the Trauma Centre Level I, the Trauma Centre Level II, with or without neurosurgery. Data are expressed as absolute values (figure 2.1) as well as in percentage (figure 2.2)

Figure 3:

Comparison of 30-day observed to expected (OE) mortality of patients affected by predominant TBI and patients affected by multiple injuries including TBI among a) the Trauma Centre Level I (Cesena) in the SIAT (Romagna) with no other neurosurgical hospitals (NSHs), b) the Trauma Centre Level I (Bologna Maggiore and Parma) in the SIATs (Emilia) with neurosurgical hospitals other than the Trauma Centre Level I, c) the Trauma Centre Level II (Ferrara, Modena Baggiovara, Reggio Emilia) in the SIATs (Emilia) with neurosurgical hospitals other than the Trauma Centre Level I.

Appendix

Appendix Table 1

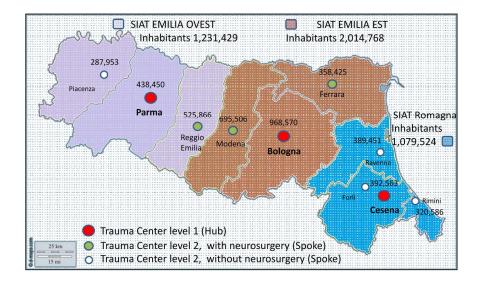
Trauma system organization and population distribution, average data per year from 2007 to 2012. Data source http://statistica.regione.emilia-romagna.it/). Data are averaged overt the years and thus the cumulative sums of the partial amounts do not correspond to the total.

Appendix Table 2

ı Cesena Types of hospitals, * not in Cesena

Appendix Figure 1

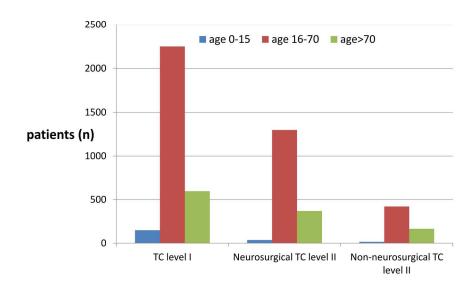
Study case material



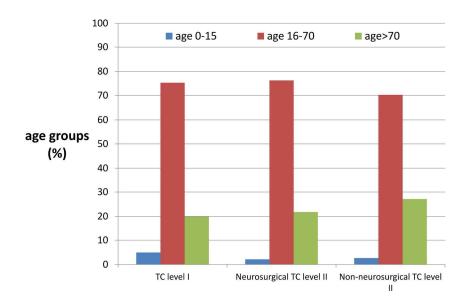
Simplified map of the Emilia Romagna region. The territory is divided into three Trauma Systems (SIATs) and the central location of the three corresponding Trauma Centres Level I (hubs) is reported. The population of each SIAT and each district referring to the Level II Trauma Centre (spoke hospital) are described.

The location and characteristics (neurosurgical versus not surgical) of the Level II Trauma Centres (spoke) are reported.

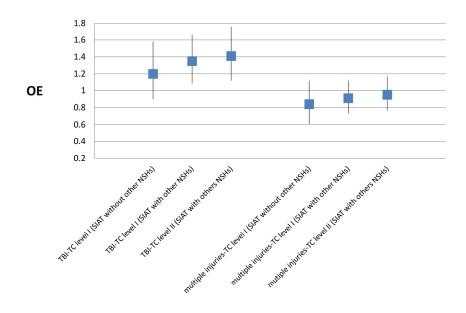




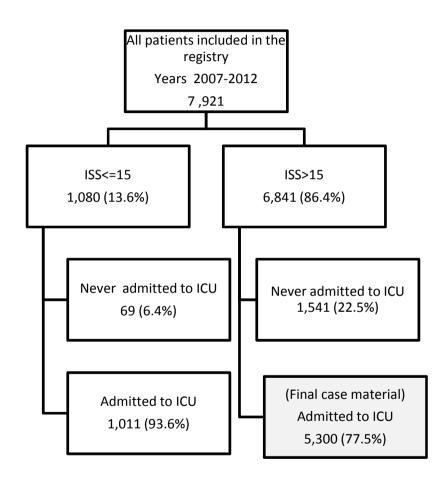
Patients distribution according to age into the Trauma Centre Level I, the Trauma Centre Level II, with or without neurosurgery. Data are expressed as absolute values (figure 2.1) as well as in percentage (figure 2.2)



Patients distribution according to age into the Trauma Centre Level I, the Trauma Centre Level II, with or without neurosurgery. Data are expressed as absolute values (figure 2.1) as well as in percentage (figure 2.2)



Comparison of 30-day observed to expected (OE) mortality of patients affected by predominant TBI and patients affected by multiple injuries including TBI among a) the Trauma Centre Level I (Cesena) in the SIAT (Romagna) with no other neurosurgical hospitals (NSHs), b) the Trauma Centre Level I (Bologna Maggiore and Parma) in the SIATs (Emilia) with neurosurgical hospitals other than the Trauma Centre Level I, c) the Trauma Centre Level II (Ferrara, Modena Baggiovara, Reggio Emilia) in the SIATs (Emilia) with neurosurgical hospitals other than the Trauma Centre Level I.



Appendix

Table 1 Trauma system organization and population distribution, average data per year from 2007 to 2012. Data Source http://statistica.regione.emilia-romagna.it/). Data are averaged overt the years and consequently the cumulative sums of partial does not fit with overall.

	Population	Trauma Centers level I	Trauma Centers	s level II
		(Hub)	(Spoke)	
Regione Emilia Romagna	4,333,088	1,479,519	2,853,56	8
	(100%)	(34.1%)	(65.9%))
			With neurosurgery	Without
				neurosurgery
			1,560,889 (57.3%)	1,163,474
				(42.7%)
SIAT				
Emilia Ovest (Parma)		1 hospital	1 hospital	1 hospital
	1,231,429	431,644 (29.2%)	517,368 (41.9%)	284,763
	(100%)			(24.5%)
		1 hospital	2 hospitals	0 hospital
Emilia Est (Bologna,	2,014,768	845,046 (57.1%)	1,043,521 (51.7%)	0
Modena, Ferrara)	(100%)			
		1 hospital	0 hospitals	6 hospitals
Romagna	1,079,524	202,829	0	878,712
	(100%)	(13.7%)		(75.5%)

Table 2, Types of hospitals, * not in Cesena

	Trauma Centers level I	Trauma Cer	nters level II			
	(Hub)	(Spoke)				
		With Neurosurgery	Without Neurosurgery			
Hospitals	3	3	7			
Trauma center level	I	П	III			
Helicopter	At the hospital*, not night flight					
Emergency abdominal or thoracic surgery	24-hour ward	24-hour ward	24-hour ward			
Cardiac surgery	24-hour ward*					
Neurosurgery	24-hour ward	24-hour ward				
Orthopedic surgery	24-hour ward*	24-hour ward	On call			
Interventional radiology	On call	On call				
Transfusion service	On call	On call	On call			
Maxillo-facial surgery	On call	On call	On call			
Trauma service	yes	No	No			
Coordination of the SIAT Trauma System	yes	No	No			

STROBE 2007 (v4) Statement—Checklist of items that should be included in reports of cross-sectional studies

Section/Topic	Item #	Recommendation	Reported on page #
Title and abstract	1	(a) Indicate the study's design with a commonly used term in the title or the abstract	1
		(b) Provide in the abstract an informative and balanced summary of what was done and what was found	2
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	3
Objectives	3	State specific objectives, including any prespecified hypotheses	4
Methods			
Study design	4	Present key elements of study design early in the paper	4
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	4-5
Participants	6	(a) Give the eligibility criteria, and the sources and methods of selection of participants	5
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	Not applicable
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	Not applicable
Bias	9	Describe any efforts to address potential sources of bias	5
Study size	10	Explain how the study size was arrived at	Nor applcable
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	5 and 6
Statistical methods	12	(a) Describe all statistical methods, including those used to control for confounding	5
		(b) Describe any methods used to examine subgroups and interactions	5
		(c) Explain how missing data were addressed	Not applicable
		(d) If applicable, describe analytical methods taking account of sampling strategy	Not applicable
		(e) Describe any sensitivity analyses	Not applicable
Results			6

			1
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility,	6
		confirmed eligible, included in the study, completing follow-up, and analysed	
		(b) Give reasons for non-participation at each stage	
		(c) Consider use of a flow diagram	Appendix, figure 1
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential	
		confounders	
		(b) Indicate number of participants with missing data for each variable of interest	
Outcome data	15*	Report numbers of outcome events or summary measures	Not applicable
Main results	16	(a) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence	Page 6-11, table 1 to
		interval). Make clear which confounders were adjusted for and why they were included	3
		(b) Report category boundaries when continuous variables were categorized	Page 6-11, table 1 to
			3
		(c) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	Not applicable
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	Not applicable
Discussion			
Key results	18	Summarise key results with reference to study objectives	11
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and	
		magnitude of any potential bias	
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from	12
		similar studies, and other relevant evidence	
Generalisability	21	Discuss the generalisability (external validity) of the study results	12
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on	13
		which the present article is based	

^{*}Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at www.strobe-statement.org.