ORIGINAL ARTICLE

Effects of 2 Patterns of Prehospital Care on the Outcome of Patients With Severe Head Injury

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Hypothesis: A pattern of prehospital care combining advanced life support, physician staffing, and helicopter transport improves the outcome of patients with severe brain injuries, compared with combined expanded basic life support, nurse staffing, and ground transport.

Design: Inception cohort from the data set of a population-based, prospective study on major trauma.

Setting: Prehospital and hospital trauma systems of an Italian region.

Patients: All patients with major trauma (Injury Severity Score, ≥16) and severe head injury (Abbreviated Injury Scale score for the head, ≥4) rescued alive from March 1, 1998, to February 28, 1999, who received either form of care. Patients with self-inflicted injuries were excluded. The 184 patients who met the entry criteria were divided equally between care groups.

Interventions: None.

Main Outcome Measures: Mortality at 30 days and Glasgow Outcome Scale score of survivors.

Results: After verifying the comparability of the cohorts, no survival or disability benefit could be demonstrated (95% confidence interval [CI] of the odds ratio for mortality [helicopter/ambulance] [95% CI 1], 0.72 to 2.67; 95% CI of the difference in Glasgow Outcome Scale score medians between helicopter and ambulance groups [95% CI 2], 0.0 to 0.0). Similar results were derived from analyses restricted to the subgroups identified by low (≤90 mm Hg) roadside systolic blood pressure (95% CI 1, 0.58 to 7.17; 95% CI 2, –1 to 2) and by need for urgent neurosurgical intervention (95% CI 1, 0.16 to 2.60; 95% CI 2, 0 to 2). Exclusion from the ambulance group of victims rescued in urban areas did not change the results (95% CI 1, 0.80 to 3.24; 95% CI 2, 0.0 to 0.0). Stratification by age, Injury Severity Score, and Glasgow Coma Scale score demonstrated a small survival benefit (95% CI 1, 1.12 to 2.12) in the ambulance subgroup with Glasgow Coma Scale score from 10 to 12. Multiple logistic regression analysis confirmed that the group did not affect mortality.

Conclusion: This study was conceived to emphasize the supposed advantages of the combined helicopter, physician, and advanced life-support rescue. No increased benefit compared with the simpler rescue group could be demonstrated.

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THE USEFULNESS of helicopter emergency services for trauma patients is controversial. In general, the advantage of these services compared with ground facilities is mainly believed to be derived from the following 2 factors: the availability of a highly qualified rescue team at the accident scene and, to a lesser extent, the transport of patients to tertiary care centers in a faster and smoother manner. Therefore, the controversy about their usefulness is linked to the larger controversy about the advantages of advanced life support (ALS) compared with basic life support (BLS) in trauma prehospital care; indeed, both issues inevitably interweave or even confuse one another in most of the literature. More confusion is added by the fact that, among the reports comparing air and ground transport, the composition of the rescue teams is far from uniform in terms of qualification, training of involved professionals, and corresponding performance level. To date, neither controversy seems close to resolution. A recent review concluded that "Whether helicopter transport is of benefit for trauma victims is still critically discussed"[1(p175)]; another found "a desperate need for prospective, randomised, controlled trials that compare ALS versus BLS prehospital care in victims of major trauma."[2(p488)]

Given this lack of evidence, the purpose of this study is to test the minimal hypothesis that a pattern of prehospital res-

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cue combining the supposed advantages of aggressive ALS procedures, physician staffing, and helicopter transport improves the outcome of major trauma in patients with severe brain injury compared with a simpler pattern combining expanded BLS, nurse staffing, and ground transport.

The choice of enrolling only patients with severe brain injuries has been made on 2 assumptions, aiming at increasing the chances to detect any advantage of the combined air transport vs the combined ground transport rescue patterns. First, brain-injured patients have been shown to benefit the most from direct transportation to tertiary

SUBJECTS AND METHODS

The data for this study are part of the Friuli Venezia Giulia Major Trauma Outcome Study (FMTOS). The FMTOS is a prospectively conducted study aimed at the setting of a regional trauma data bank to gather better information on the epidemiology of trauma and to foster a continuous quality-improvement process in trauma care. The study was performed from March 1, 1998, through February 28, 1999, in Friuli Venezia Giulia (FVG), a small region in northeastern Italy. The FMTOS included all patients who sustained a traumatic injury within the regional borders and who either died in the prehospital setting or were admitted to any of the FVG hospitals. All patients with an Injury Severity Score (ISS)[6] of less than 16 and patients whose injuries were self-inflicted were excluded from the study. The victims found dead on the scene were included in the study but underwent separate analysis. The following prehospital data of patients enrolled in the FMTOS were collected: demographic factors; mechanism, place, and time of injury; time intervals; type of intervening rescue facility; on-scene vital signs (respiratory rate, oxygen saturation, systolic blood pressure [SBP], Glasgow Coma Scale [GCS] score, and Revised Trauma Score [RTS][7]); and interventions. The recorded hospital data included time intervals, consultations, interventions, time of their performance, and patients' destination (department). Patients were followed up at regular intervals to record the time of death or discharge from the intensive care unit and, through the detailed diagnosis or the postmortem findings, the Abbreviated Injury Scale[8] (AIS), the ISS, and the Prognostic Severity Index (TRISS).[9] The Glasgow Outcome Scale (GOS) score[10] of the patients alive at 30 days after admission was recorded (at 6 months). The FVG Regional Agency for Health approved the study. The study was exempted from procurement of informed consent because of the absence of any treatment and the anonymity of the stored data. The FMTOS is described in detail by Nardi et al.[11]

The FVG has a surface area of 7846 km^2 and a population of 1 184 000, about 400 000 of whom live in the 4 major urban areas. The region has 2 level I trauma centers and several smaller hospitals. A prehospital Regional Emergency Medical Service (EMS) has been working in FVG since 1992. The FVG EMS consists of 4 province-based call centers that receive the emergency calls and that dispatch and coordinate the activity of ground ambulances and the Helicopter Emergency Medical Service (HEMS). The ground ambulances are staffed by a nurse who is exclusively devoted to emergency services and by 1 or, more often, 2 drivers. Most of the drivers have received layperson BLS training. During the study, physicians of heterogeneous background, education, and skills used joined the nurses in some subregional districts on the same ambulances or with special cars. The HEMS operates 1 rotorcraft in daytime only. The helicopter crew consists of a pilot, an anesthetist with multiyear certified experience in trauma care, and 2 registered nurses with long-term experience in intensive care unit or prehospital emergency care. One of the nurses acts as flight coordinator.

In terms of basic trauma care (extrication, immobilization, and oxygen administration), the performances of ground and airborne rescue teams are to be considered comparable. The only exception is that the airborne team, once the rotor has stopped, invariably consists of 3 people, whereas the ground team, in a few cases, consists of 2. The advanced medical procedures expected and effectively performed during the study period by both types of rescue services are described in **Table 1**.

The FVG ambulance nurses, in addition to strict BLS[12] procedures, perform fluid administration, and, when cardiac arrest occurs, defibrillation plus injection of epinephrine and atropine. Ambulance teams do not use any standardized regional operative protocol. On the other hand, HEMS policy complies with the guidelines of the Italian Resuscitation Council for prehospital care.[13] These guidelines recommend the following pressure targets for fluid resuscitation: SBP of greater than 90 mm Hg in blunt trauma and greater than 110 mm Hg in blunt trauma with head injuries. Although both types of services give intravenous infusions, only HEMS is committed to pursuing these targets aggressively in terms of number and size of intravenous lines placed and amount of fluids given. In a previous study,[14] the mean (±SD) quantity of fluids given by HEMS to patients with SBP of no greater than 90 mm Hg was as high as 2344 ± 2375 mL.

As an experienced anesthetist is part of the HEMS crew, endotracheal intubation is always accomplished with a proper induction of anesthesia to prevent any increase of intracranial pressure.

Calls to FVG EMS are processed following an advanced medical priority protocol in 1 center and a criterion-based system in the other 3 centers. The helicopter is dispatched only for traumatic injuries according to a situational protocol. An ambulance is always dispatched simultaneously with the helicopter. When the ambulance crew reaches the scene before the helicopter, and the clinical conditions of the patients are estimated not to be serious, the nurse can, after consulting with the flying physician, abort the mission. On the other hand, if the ambulance crew happens to attend a case worse than expected, intervention of HEMS can be requested in a 2-tiered fashion.

The HEMS base is located at the geographical center of the region, so that any place can be reached within a maximum 20-minute flight. The ambulances are located so that they can reach any target in a maximum of 8 minutes in urban areas and 20 minutes in rural areas. The HEMS is not dispatched to urban areas as a rule, although in the 2 urban areas of FVG without a level I trauma center, a rendezvous is usually arranged at the nearest suitable landing place at the request of the ambulance nurse. In this case, patients undergo further evaluation and treatment according to HEMS protocols before boarding. Under these circumstances, patients were considered as attended by HEMS (n=5).

The present study includes all the patients in the FMTOS with severe head injury who were found alive by the first rescue team. The patients attended by ground ambulances with a physician on board or taken

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to the hospital by private means were subsequently excluded. Severe head injury was defined as an AIS score of the head of at least 4.

The following 2 cohorts of major trauma patients with severe brain injuries were identified: group A, attended by HEMS and physician, and group B, attended by ambulance and nurse. Patients in group B were not attended by HEMS for the following reasons: darkness (56 [61%]), urban area (10 [11%]), busy with another intervention (9 [10%]), mistake of dispatching operator (8 [9%]), mechanism of injury outside dispatch protocol (6 [7%]), and intervention aborted by ambulance nurse (3 [3%]). No HEMS attendance was aborted as a result of adverse weather.

The enrolled patients are described by mechanism of injury, sex, age, ISS, GCS, RTS, and TRISS. We also described the need for interhospital referral within 48 hours of admission and time intervals from call to arrival of rescue facilities, from call to arrival at emergency department, and from call to arrival at the emergency department of the definitive-treatment hospital. The characteristics deemed important to test the homogeneity of the groups, allowing the subsequent comparison of outcome, are age, ISS, and RTS. The outcome measures used in the study are trauma death (within 30 days after admission) and GOS.

Three subgroups that were not mutually exclusive and where the supposed benefits of helicopter transport could be more evident were individuated within the above-defined cohorts. One subgroup consisted of patients with low (≤90 mm Hg) SBP on the scene. They were selected because they should benefit from a more aggressive prehospital fluidotherapy. Patients who required urgent craniotomy made up the second subgroup, because prompt access to the trauma center may have a special influence on their outcome. The third analysis excluded group B patients rescued in the urban areas in which the 2 regional trauma centers are located. Because of the close proximity of the treatment hospital, prehospital care may play a minor role in those patients, and the differences between the rescue patterns may be blurred. Any subgroup from group A was then compared with its peer from group B to detect any significant difference in the variables chosen to warrant homogeneity; if homogeneity was confirmed, comparison of the outcome variables was performed.

Continuous variables (age and time intervals) are displayed as mean±SD. Ordinal variables (ISS, RTS, GCS, TRISS, and GOS) are displayed as mean and median.

The size and statistical significance of the differences between continuous variables in both groups were determined by calculating the confidence interval (CI) for the difference between means (DBM) using the following equation:

$$\text{CI for DBM} = \text{DBM} \pm (1.96 \times \text{SE of DBM}).$$

The ordinal variables were not normally distributed and were analyzed using the nonparametric Mann-Whitney test, whose results are displayed as 95% CI of the difference between medians. The 95% CI for the difference between proportions (DBP) was determined using the following equation:

$$\text{CI for DBP} = \text{DBP} \pm (1.96 \times \text{SE of DBP}).$$

The DBP was computed for nominal variables (mechanism of injury, sex, and interhospital referral).

The choice of the CI to describe the size of the differences between groups has been made for the reasons explained by Brown and Swanson Beck.[15] When the CI does not straddle 0, there is a 95% chance that a difference, whose size is within the range of the CI itself, is present. For the purposes of this report, the difference is considered significant whenever this occurs.

For the nominal variable trauma death, the odds ratio (OR) and corresponding 95% CI were computed. The OR is a mathematical expression of the relative risk for an event (in this case trauma death) occurring when a risk factor is present (eg, belonging to the group rescued by helicopter). An OR of 2.0 means that death is 2 times more likely to occur if HEMS is the rescue facility; an OR of 0.5, that death is 2 times more likely to occur if ambulance intervenes; and an OR of 1.0, that there is no difference between the groups. Therefore, a 95% CI of an OR that does not encompass 1.0 corresponds to a 95% probability that the groups are different.

Although they never reach significance, some differences exist between the groups and subgroups about demographic and severity indexes. Therefore, 2 alternative approaches were devised to compensate for these minor differences. Stratification of patients by age, ISS, and GCS was the first approach. Age was stratified in just 2 clusters (≤14 and >14 years), because a different distribution of children, whose prognosis is known to be better,[16] may escape identification through DBM, but may affect outcome results. Stratification by ISS and GCS reduces the number of patients in each class, but has the advantage of exploring classes of defined trauma severity where the benefits of helicopter transport may be more evident, as hinted by previous studies.[17]

The second alternative approach was a multiple logistic regression analysis with trauma death as dependent variable and age, sex, ISS, RTS, and pattern of prehospital rescue as independent predictors.

The only descriptive characteristic whose difference between the groups reaches statistical significance is the mechanism of injury. It is a common opinion that, irrespective of prognostic indexes, patients with low-velocity injuries, such as falls, tend to do more poorly than those with high-velocity injuries, such as traffic accidents. For this reason, despite the fact that the mechanism of injury is not a variable selected to warrant homogeneity, a further analysis of outcome was performed after excluding the patients listed with a fall as the mechanism of injury.

care centers.[3,4] This policy is usually more common outside urban areas if on-scene medical triage and helicopter transport are available. Second, since these patients have been demonstrated to be particularly sensitive to any episode of hypotension and/or hypoxia,[5] they should receive maximum advantage from top-level prehospital clinical care.

RESULTS

A total of 251 patients were entered into the study. They all had major trauma and severe head injuries and were found alive by the first rescue team. Ninety-two of them were rescued by HEMS, and 92 were rescued by nurse-

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led ground ambulances. They constitute the 2 cohorts under scrutiny. Sixty-two patients were rescued by physician-led ground ambulances. Five patients reached the hospital by private means. These 2 latter groups were excluded from the study.

Table 2 shows the characteristics of both cohorts, their outcome measures, and the results of the comparison between all these variables. Briefly, in addition to a substantial homogeneity of demographics and severity of injuries, no significant difference in outcome was found. The main differences were observed in mechanism of injury, time intervals, and frequency of interhospital transfers. Falls were less represented in group B. The patients of this group reached the first hospital in about half the time than taken by group A patients. However, they required urgent interfacility transfer much more frequently; therefore, they reached the definitive hospital with consistent delay.

Table 3 depicts the special analysis of outcome after exclusion of patients whose injuries were caused by falls. No difference between groups was present.

Stratification of patients by age, ISS, and GCS and comparison between the outcome variables of the subgroups so identified are displayed in **Table 4**. Again, no difference was found between cohorts, except for patients with GCS from 10 to 12, who were more likely to die when HEMS was the rescue facility.

Table 1. Medical Procedures Expected by Rescue Facilities and Rate of Actual Performance*

Procedures Expected and Usually Performed	Rate of Performance, No. (%) Group A (n = 92)	Group B (n = 92)
Ventilation†	64 (70)	Not recorded
Cricothyroidotomy	0‡	. . .
Chest drainage	4 (4)	. . .
Pericardiocentesis	0‡	. . .
Peripheral or central large bore intravenous line(s)§	92 (100)	74 (80)
Intravenous fluids	89 (97)	60 (65)
Medications‖	Not recorded	0‡
Defibrillation	0‡	0‡

*Groups are described in the "Subjects and Methods" section.
†Indicates tracheal intubation for helicopter transport; bag-mask ventilation for ambulance transport. For tracheal intubation, rate was 100% for Glasgow Coma Scale (GCS) score <9; 58% when GCS score was 10-12.
‡None were needed.
§Includes peripheral intravenous lines only for ambulance transport.
‖Indicates expanded medications for helicopter transport; limited medications (cardiac arrest only) for ambulance transport.

Table 3. Outcome of Patients and Comparison After Exclusion of Falls as Mechanism of Injury*

	Group A (n = 74)	Group B (n = 88)	95% CI of the Difference Between Groups
Trauma deaths, No. (%)	23 (31)	20 (23)	0.76 to 3.09 (OR, 1.533)
GOS, mean (median)	4.1 (5)†	4.0 (5)‡	0.0 to 0.0§

*Groups are described in the "Subjects and Methods" section. GOS indicates Glasgow Outcome Scale score; CI, confidence interval.
†n = 41.
‡n = 51.
§Mann-Whitney test.

Table 2. Characteristics and Outcome of Patients*

	Group A (n = 92)	Group B (n = 92)	95% CI of the Difference Between Groups
Blunt injury, No. (%)	92 (100)	92 (100)	. . .
Mechanism of injury			
Traffic	65 (71)	77 (84)	−0.25 to −0.01†
Fall	18 (20)	4 (4)	0.06 to 0.24†‡
Other	9 (10)	11 (12)	−0.11 to 0.07†
Male, No. (%)	76 (83)	66 (72)	−0.01 to 0.23†
Age, mean ± SD, y	46.8 ± 21.1	42.2 ± 22.4	−1.7 to 10.9§
ISS, mean (median)	33.4 (25)	30.0 (25)	−2.0 to 4.0‖
GCS, mean (median)	9.2 (9.5)	9.2 (8.0)¶	−1.0 to 1.0‖
RTS, mean (median)	5.9 (6.3)	5.9 (6.1)#	−0.5 to 0.2‖
TRISS, mean (median)	64.2 (86.0)	70.6 (90.0)#	−6.7 to 1.9‖
Interhospital referral, No. (%)	4 (4)	41 (45)	−0.53 to −0.28†‡
Intervals, mean ± SD, min			
Call to arrival at patient	9.6 ± 6.4	8.7 ± 7.1	−1.0 to 2.9§
Call to arrival at first hospital	64.2 ± 27.3	33.8 ± 16.8	23.8 to 37.0‡§
Call to arrival at definitive hospital	68.9 ± 30.2	126.6 ± 127.3	−84.8 to −30.7‡§
Trauma deaths, No. (%)	28 (30)	22 (24)	0.72 to 2.67 (OR, 1.39)
GOS, mean (median)	4.2 (5)**	4.0 (5)††	0.0 to 0.0

*CI indicates confidence interval; ISS, Injury Severity Score; GCS, Glasgow Coma Scale score; RTS, Revised Trauma Score; TRISS, Prognostic Severity Index; OR, odds ratio (group A/B); and GOS, Glasgow Outcome Scale score. Groups are described in the "Subjects and Methods" section.
†Indicates difference between proportions, described in the "Subjects and Methods" section.
‡Indicates significance, described in the "Subjects and Methods" section.
§Indicates difference between means, described in the "Subjects and Methods" section.
‖Mann-Whitney test.
¶n = 84.
#n = 81.
**n = 53.
††n = 52.

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Table 4. Outcome Stratified by Age, ISS, and GCS*

	Group A (n = 92)			Group B (n = 92)			Statistics	
	No. (%)			No. (%)				
Measure	Trauma Death	Survival	GOS, Mean (Median)	Trauma Death	Survival	GOS, Mean (Median)	Mortality OR (95% CI)	GOS (A – B), 95% CI†
Age, y								
0-14	0	4 (100)	5.0 (5) (n = 2)	0	2 (100.0)	5.0 (5) (n = 1)	. . .	. . .
>14	28 (32)	60 (68)	4.2 (5) (n = 51)	22 (24)	68 (76)	3.9 (5) (n = 51)	1.44 (0.75 to 2.78)	0.0 to 0.0
ISS								
16-25	6 (12)	42 (88)	4.6 (5) (n = 31)	9 (19)	39 (81)	4.1 (5) (n = 26)	0.62 (0.2 to 1.9)	0.0 to 0.0
26-35	4 (29)	10 (71)	3.7 (4) (n = 10)	4 (22)	14 (78)	3.7 (4.5) (n = 12)	1.4 (0.28 to 6.97)	−1.0 to 2.0
36-45	3 (27)	8 (73)	3.5 (4) (n = 8)	3 (21)	11 (79)	4.5 (5) (n = 8)	1.38 (0.22 to 8.67)	−3.0 to 0.0
46-66	8 (67)	4 (33)	4.0 (4) (n = 4)	5 (45)	6 (54)	3.2 (3) (n = 6)	2.4 (0.44 to 12.98)	−1.0 to 3.0
75	7 (100)	0	. . .	1 (100)	0	. . .	3.6 (0.7 to 18.56)	. . .
GCS								
3	12 (75)	4 (25)	3.3 (3.5) (n = 4)	5 (46)	6 (54)	2.4 (3) (n = 5)	3.6 (0.7 to 18.55)	−2.0 to 4.0
4-6	4 (40)	6 (60)	3.8 (4) (n = 5)	9 (43)	12 (57)	3.9 (5) (n = 11)	0.89 (0.19 to 4.11)	−2.0 to 2.0
7-9	7 (35)	13 (65)	3.9 (4) (n = 12)	2 (14)	12 (86)	4.5 (5) (n = 8)	3.23 (0.56 to 18.71)	−2.0 to 0.0
10-12	4 (24)	13 (76)	4.2 (5) (n = 8)	0	7 (100)	4.3 (4.5) (n = 6)	1.54 (1.12 to 2.12)‡	−1.0 to 1.0
13-15	1 (3)	28 (97)	4.5 (5) (n = 24)	3 (10)	28 (90)	4.0 (5) (n = 18)	0.33 (0.03 to 3.4)	0.0 to 1.0
Missing	. . .	. . .	. . .	3 (38)	5 (62)	4.3 (4.5) (n = 4)	. . .	. . .

*Groups are described in the "Subjects and Methods" section. Abbreviations are described in the first footnote to Table 2. Percentages have been rounded and may not sum 100. Ellipses indicate not applicable or available.
†Mann-Whitney test.
‡Indicates significance, described in the "Subjects and Methods" section.

When the analysis was restricted to hypotensive patients, the 2 cohorts appear less homogeneous but still comparable and, again, no difference in outcome was found, as shown in **Table 5**.

Taking into account solely the patients requiring urgent neurosurgery, the yield is similar, except that in this subgroup the trend toward a lower mortality for ambulance patients was reversed in favor of HEMS. **Table 6** summarizes these findings.

The exclusion of the patients rescued in urban areas with level I trauma centers does not modify the outcome results, as shown in **Table 7**.

A multiple logistic regression model was built using trauma death as the dependent variable and the pattern of prehospital rescue, sex, age, ISS, and RTS as independent predictors (overall model significance, $P<.001$) (**Table 8**). This model once again showed that the pattern of prehospital rescue did not affect mortality (Wald statistic, $P=.68$).

Table 5. Characteristics and Outcome of Patients With Systolic Blood Pressure of No Greater Than 90 mm Hg*

	Group A (n = 21)	Group B (n = 20)	95% CI of Difference Between Groups
Age, mean ± SD, y	44.5 ± 21.9	32.1 ± 18.5	−0.5 to 25.2†
Male, No. (%)	18 (86)	15 (75)	−0.14 to 0.35‡
ISS, mean (median)	46.7 (50)	38.8 (40.5)	−5.0 to 21.0§
RTS, mean (median)	3.5 (2.9)	3.9 (3.8)	−1.6 to 0.9§
TRISS, mean (median)	26.2 (6.3)	37.3 (21.3)	−22.5 to 1.6§
Trauma deaths, No. (%)	11 (52.4)	7 (35.0)	0.58 to 7.17 (OR, 2.04)
GOS, mean (median)	3.7 (4)‖	3.4 (4)¶	−1.0 to 2.0§

*Abbreviations are described in the first footnote to Table 2. Groups are described in the "Subjects and Methods" section.
†Indicates difference between means, described in the "Subjects and Methods" section.
‡Indicates difference between proportions, described in the "Subjects and Methods" section.
§Mann-Whitney test.
‖n = 9.
¶n = 12.

COMMENT

A major limitation of this report is the mechanism of allocation of patients to the groups. Randomization is an essential requirement for a comparative study to lead to valid conclusions. It is also true that, once some standards of care are established, it is considered unethical to withhold them for research purposes, even if their usefulness is scientifically controversial. This applies also to prehospital care, where it would not be acceptable to randomize patients to receive HEMS or ambulance care when the former is available. The HEMS is available in daytime only and operates a single rotorcraft that cannot land in urban areas. These are the main reasons for its missed interventions, namely the criteria of entry to group B of prehospital care (ambulance-nurse-BLS). Whether these criteria imply any selection bias compared with pure randomization is a crucial question. Five of the criteria (urban area, busy with another mission, mistake of dispatching operator, inadequacy of dispatch protocol, and intervention aborted by ambulance nurse) account for 40% of cases and seem unlikely to cause any major bias. The criterion accounting for most entries (56 [61%]) to group B is the occurrence of traumatic event during nondaylight hours. A wealth of epidemiological studies on trauma shows that nighttime traffic accidents are associated with increased alcohol consumption[18] and young

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Table 6. Characteristics and Outcome of Patients Requiring Urgent Neurosurgery*

	Group A (n = 14)	Group B (n = 26)	95% CI of the Difference Between Groups
Age, mean ± SD, y	36.1 ± 18.4	47.6 ± 20.0	−24.4 to 1.3†
Male, No. (%)	9 (64)	19 (73)	−0.39 to 0.21‡
ISS, mean (median)	31.2 (25)	30.1 (25)	−5.0 to 8.0§
RTS, mean (median)	6.3 (6.4)	5.9 (5.9)‖	−0.9 to 1.8§
TRISS, mean (median)	76.4 (91.7)	66.7 (83.1)‖	−5.2 to 28.9§
Trauma deaths, No. (%)	4 (29)	10 (38)	0.16 to 2.60 (OR, 0.64)
GOS, mean (median)	4.9 (5)¶	3.7 (5)#	0.0 to 2.0§

*Abbreviations are given in the first footnote to Table 2. Groups are described in the "Subjects and Methods" section.
†Indicates difference between means, described in the "Subjects and Methods" section.
‡Indicates difference between proportions, described in the "Subjects and Methods" section.
§Mann-Whitney test.
‖n = 22.
¶n = 7.
#n = 11.

Table 7. Characteristics and Outcome of All Group A Patients vs Group B Patients Not Rescued in Urban Areas With Level-I Trauma Center*

	Group A (n = 92)	Group B (n = 82)	95% CI of the Difference Between Groups
Age, mean ± SD, y	46.8 ± 21.1	42.0 ± 22.3	−1.7 to 11.3†
Male, No. (%)	76 (83)	58 (71)	−0.01 to 0.24‡
ISS, mean (median)	33.4 (25)	30.5 (29)	−4.0 to 4.0§
RTS, mean (median)	5.9 (6.3)	5.9 (6.0)‖	−0.5 to 0.3§
TRISS, mean (median)	64.2 (85.9)	70.9 (87.7)‖	−7.0 to 2.0§
Trauma deaths, No. (%)	28 (30)	17 (21)	0.80 to 3.24 (OR, 1.61)
GOS, mean (median)	4.2 (5)¶	3.94 (5)#	0.0 to 0.0§

*Abbreviations are given in the first footnote to Table 2. Groups are described in the "Subjects and Methods" section.
†Indicates difference between means, described in the "Subjects and Methods" section.
‡Indicates difference between proportions, described in the "Subjects and Methods" section.
§Mann-Whitney test.
‖n = 73.
¶n = 53.
#n = 47.

age.[19] Nighttime occurrence is commonly perceived as a risk factor for fatal injuries. This perception does not seem to be confirmed by 2 recent studies addressing risk factors in traffic accidents.[20,21] Moreover, strictly nighttime hours are only a minor fraction of darkness hours, particularly in winter, when HEMS activity ends at midafternoon. Inferences from epidemiological data on nighttimes accidents are, however, only marginally pertinent to the present study, where the demographics and severity of injuries in both groups are known and appear homogeneous at an acceptable level.

The uniformity between the groups in the type of injury (blunt vs penetrating) is absolute, whereas a significant difference exists in the specific mechanism of injury. Falls are less represented in the ambulance group, probably reflecting a lower incidence of work-related accidents during nighttime. Again, this difference, however limiting the theoretical intergroup homogeneity, should hardly be considered influential for the scopes of the study, provided the factors determining the probability of survival (demographics, physiological derangement, and severity of injuries) are controlled for. At all events, the outcome results do not change, even when excluding the victims of falls.

Table 8. Multiple Logistic Regression Analysis With Trauma Death as the Dependent Variable*

Independent Variable	*P* Value†
Age	<.001‡
Sex	.94
ISS	.001‡
RTS	.002‡
Pattern of prehospital rescue	.68

*Overall significance, $P<.001$; Hosmer-Lemeshow goodness-of-fit test, 0.0964 (if >0.05, the model's estimates fit the data at an acceptable level). ISS indicates Injury Severity Score; RTS, Revised Trauma Score.
†Wald statistic.
‡Significant ($P<.05$).

Another possible source of bias is a different hospital treatment given to patients in the 2 groups. The HEMS and ambulance patients had access to each of the 2 FVG trauma centers in equal proportions (data not reported). Both types of rescue teams are equally entitled to preemptive activation of hospital facilities (eg, universal blood and trauma team). Hence, the subsequent course of patients of both groups can be assumed to be identical once they arrived at the hospital. The higher chances of HEMS patients gaining direct access to the definitive-treatment hospital are a characteristic of that rescue pattern and not a confounding factor. It can be argued, however, that nighttime overall performances of hospitals are worse than daytime ones, at the expense of ambulance patients. This bias is impossible to exclude. Nevertheless, even if existing, this bias must be very small, for it was never detected in any of the yearly reports from the regional hospitals. Its importance, then, is further diminished by the previously mentioned fact that strictly nighttime hours are a minor part of HEMS nonoperative hours. In addition, the common belief that sleep deprivation reduces the efficiency of hospital staff has never found scientific confirmation.[22]

This study has been fashioned to increase the chances of detecting the supposed superiority of one pattern of rescue over the other. Any possible bias seems to go in the same direction. However, its results are somewhat opposite to expectations. Minor differences in ISS, age, and consequently TRISS cannot explain these results, because multiple logistic regression analysis confirmed them. Moreover, the expected correspondence between the direction of the nonsignificant intergroup differences in factors affecting probability of survival and the corresponding nonsignificant differences in outcome seems to be verified. In other words, the possible presence of a trend toward a better survival in one group or subgroup can

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be explained by a trend toward better chances of survival in the same group. Nevertheless, a different distribution of ISS may have influenced outcome but gone undetected by statistical testing, since the relationship between ISS and mortality may be not linear. Stratification can correct this possible flaw, and indeed it shows that the distribution of patients with overwhelming injuries (ISS=75) is uneven, ie, 7 patients in group A and 1 patient in group B. Unfortunately, the results of outcome comparison do not change, even after excluding these patients and thus maximizing homogeneity (data not reported).

Another incidental finding of the stratification by ISS is that the results of Nicholl et al,[17] who showed an increased survival benefit of helicopter rescue as the severity of injuries increased, are not confirmed by our study.

The GOS figures seem less affected by minor intergroup heterogeneity, the mean GOS score being always slightly higher in group A.

A type II error might explain this study's results; however, this explanation does not seem applicable because, as mentioned, the nonsignificant trends always go in the predictable direction. There is even a significant survival advantage of the ambulance pattern of rescue in a small subcategory of patients. Besides, the nearly 100 patients in each group represent a purposeful selection of a population of more than a million followed up for 1 year. To build a more powerful study would not be a trivial task.

Although surprising, these results are not in contrast with those of previous studies. The assessment of London HEMS benefits on survival after trauma yielded similar conclusions.[17] At present, evidence against ALS and/or invasive maneuvers performed outside the hospital in trauma patients is undergoing a resurgence,[23-25] whereas the classic reports favoring the helicopter-ALS-physician combination[26,27] date back nearly 15 years. Exploring in detail the thorny matter of ALS vs BLS is beyond the scopes of this report. This temporal shift is similar to what happened in FVG where a 1992 study comparing mortality of severe trauma patients between HEMS and ambulance transport demonstrated a striking difference (12% vs 38%).[28] A constant process of training and education of ambulance staff followed. This change could be a key point, and the quality of BLS may make the difference. When FVG HEMS was first launched in 1992, it embodied the modern, efficient principles of prehospital trauma care. In the following years, thanks to a praiseworthy regional educational policy, the essential part of these principles spread and became known and appreciated among all personnel. Combined with other logistic and technological improvements of FVG EMS, this change may have reduced the demonstrable benefits of HEMS.

An alternative explanation for the findings of this study is that some of the maneuvers included in the ALS standard of treatment are not scientifically recognized as helpful. For example, prehospital fluid administration is not unanimously accepted as useful. If its harmfulness were to be confirmed in the future, the aggressive HEMS approach presently justified by all the main worldwide guidelines might counterbalance and mask the benefits of other useful interventions (eg, pneumothorax decompression and centralization to trauma centers). Although the ambulance teams of this study administered fluids in a number of cases, this procedure is not strictly part of the BLS standard of care. Still, this is a point of difference and not of similarity between the patterns of rescue under study. There are indeed wide qualitative and quantitative differences between the 2 types of rescue teams in performing this procedure (Table 1).

The baseline assumption of this report, that the severely brain-injured patients take special advantage of high-level prehospital care, might also be wrong. The assumption is arbitrary and not evidence based. However, at the present state of the art, it should be accepted on the grounds of the same principles that rule the current treatment of trauma patients.

Another hypothesis that needs to be ruled out is that the performances of FVG HEMS are suboptimal. Once more, this does not seem to be the case, since the percentages of effectively performed procedures and the absolute figures of mortality are both well in accordance with, if not lower than, the international standards. The figures of interfacility referrals further demonstrate that the opportunities to triage the patients to the appropriate hospital offered by the rotorcraft have been fully exploited, although they did not turn into better outcomes for patients. A combined analysis of the figures of time intervals and interfacility referrals also shows, as previous studies did, that the delayed arrival of helicopter-transported patients at the hospital is deceptive. It is true that they arrive at the first hospital later than do ambulance patients. However, in most cases, they go directly to the right hospital by virtue of roadside stabilization and the higher clinical judgment received. By contrast, ambulance-transported patients require interhospital transfer in nearly half of the cases, despite earlier hospital attention; this leads to consistent delay in arrival at the definitive-treatment hospital.

CONCLUSIONS

This study failed to demonstrate the minimal hypothesis put forward in the introduction section about any outcome benefit brought about by a combined ALS, physician-led, and rotorcraft-flown prehospital team. These results are surprising, because the analysis was conceived to allow for maximal expression of any possible benefit. A univocal explanation for these results could not be found. These findings, however, seem to agree with the recent reconsideration of the effects of ALS on trauma patients in the prehospital setting. Until more evidence is added, these results should not be regarded as definitive but as a stimulus to a further insight into our daily practice. The HEMS pattern of rescue gives better results in some subgroups of patients (Table 6). Although this could be explained by minor intergroup heterogeneity, it suggests that specific categories of trauma patients may require different types of prehospital care.

Since not even this minimal hypothesis could be demonstrated, new suggestions from the ongoing research process in the direction of a careful assessment of the benefits, or otherwise, of every single component of prehospital rescue are strongly needed.

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