Title: Outcomes following trauma laparotomy for hypotensive trauma patients: a UK military and civilian perspective.

Short Title: Trauma laparotomy outcomes in two UK cohorts

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Abstract

Background

The management of trauma patients has changed radically in the last decade and studies have shown overall improvements in survival. However, reduction in mortality for the many may obscure a lack of progress in some high-risk patients. We sought to examine the outcomes for hypotensive patients requiring laparotomy in UK military and civilian cohorts.

Methods

We undertook a review of two prospectively maintained trauma databases; the UK Joint Theatre Trauma Registry (JTTR) for the military cohort (4th February 2003 to 21st September 2014), and the trauma registry of the Royal London Hospital MTC (1st January 2012 to 1st January 2017) for civilian patients. Adults undergoing trauma laparotomy within 90 minutes of arrival at the Emergency Department (ED) were included.

Results

Hypotension was present on arrival at the ED in 155/761 (20.4%) military patients. Mortality was higher in hypotensive casualties 25.8% vs 9.7% normotensive casualties (p<0.001). Hypotension was present on arrival at the ED in 63/176 (35.7%) civilian patients. Mortality was higher in hypotensive patients 47.6% vs 12.4% normotensive patients (p<0.001). In both cohorts of hypotensive patients neither the average injury severity, the prehospital time, the ED arrival SBP, nor mortality rate changed significantly during the study period.

Conclusions

Despite improvements in survival after trauma for patients overall, the mortality for patients undergoing laparotomy who arrive at the Emergency Department with hypotension has not changed and appears stubbornly resistant to all efforts. Specific enquiry and research should continue to be directed at this high-risk group of patients.

Level of Evidence:
IV; Observational Cohort Study

Key words:

Laparotomy, Resuscitation, Shock, Emergencies, Military

BACKGROUND

Each year 1.5 million people die from haemorrhage after traumatic injury and bleeding remains the main cause of preventable death in both civilian and military environments. (1) In the United States (US) and more recently the United Kingdom (UK), the introduction of trauma networks has delivered measurable improvements in the survival of major trauma patients. (2, 3) During the recent conflicts in Iraq and Afghanistan, scrutiny of outcomes within deployed military healthcare systems has also confirmed incremental improvements in survival, year on year. (4) Improvements in military trauma care have occurred at all points along the chain of casualty care from point of wounding to rehabilitation (5, 6); with widespread introduction of the principles of damage control resuscitation and surgery. (7, 8) Similar changes in management have occurred in civilian settings; however, data have recently emerged from US Level 1 Trauma Centres that suggests that, for some high-risk patients, outcomes may not have improved.

In 2002, Clarke and co-workers reported the mortality rate of hypotensive trauma patients undergoing emergent laparotomy within an established US trauma system was 40%. They demonstrated the probability of death was proportional to the time to laparotomy (up to 90 minutes) and the degree of hypotension. (9) In 2017, Harvin and co-workers released data from twelve US Level 1 Trauma Centres that revealed the average mortality rate for a contemporary series of hypotensive patients undergoing laparotomy within 90 minutes was 46%. (10) This thought-provoking study motivated us to define outcomes for hypotensive patients who underwent trauma laparotomy in two contemporary UK trauma systems: a deployed military combat casualty care system and a civilian Major Trauma Centre (MTC) in the UK's capital city.

METHODS

This was a review of two prospectively maintained trauma databases; the UK Joint Theatre Trauma Registry (JTTR) for the military cohort (4th February 2003 to 21st September 2014), and the trauma registry of the Royal London Hospital MTC (1st January 2012 to 1st January 2017). Military patients were from the conflicts in Iraq and Afghanistan, treated in UK-led coalition medical treatment facilities (MTFs). The civilian patients were from an urban MTC served by London's Air Ambulance; a physician and paramedic-based prehospital helicopter emergency trauma service.

Both databases record patient demographics, injury details, admission physiology, utilization of fluid and blood products for resuscitation, surgical intervention and survival outcomes. The databases were searched for the procedure 'laparotomy'. All adult patients who underwent emergent laparotomy were included. Patients undergoing laparotomy within 90 minutes of admission to the Emergency Department (ED) were analysed as a sub group according to Harvin's study protocol, (10) with hypotension defined as a systolic blood pressure (SBP) <90 mmHg on ED admission.

Pre-hospital blood for transfusion was available in the military cohort from July 2008 and in the civilian cohort from March 2012. The military prehospital blood transfusion consisted of packed red blood cells (PRBC) with plasma (FFP) in a 1:1 ratio to a maximum of eight units. In the civilian service, prehospital transfusion support was PRBC only, each crew carrying 2 units. Each prehospital service developed protocolised transfusion triggers. (11, 12)

Statistical analysis

Normally distributed continuous data were reported as mean (with standard deviation), skewed or ordinal data were reported as medians (with interquartile range (IQR)). Chi-square or Fisher's exact tests were used for categorical data, and the unpaired t-test or Mann Whitney test for normally distributed and non-parametric data respectively. The Mantel-Haenszel test was used for trend analysis. A p-value of <0.05 was considered statistically significant. Logistic regression analysis was used to identify independent predictors of mortality and estimate odds ratios (OR). Variables with a p value of <0.1 on univariate analysis were included in the initial multivariable analysis. Non-linear terms of the continuous covariates were tested and added to the multivariate model if found to be statistically significant. Backwards model selection was used to remove insignificant terms until a final model was reached. Odds ratios and 95% confidence intervals (CI) are reported. Collinearity among continuous variables was tested using the variance inflation factor method. Year in cohort is defined as the year from the start of cohort data collection period and Severe traumatic brain injury is defined as an Abbreviated Injury Severity Score Head $\geq$ 4. Statistical analysis was performed using SPSS 25 (Chicago, IL, USA) and R, R-3.5.0 (Vienna, Austria) through RStudio v. 1.1.447 (Boston, MA, USA) with car package.

The study was approved and registered with the Medical Directorate, Joint Medical Command, and with the Audit Governance team at the Royal London Hospital.

RESULTS

The JTTR contained 9,538 casualties injured or killed during the study period (2003-2014). 821 (8.6%) casualties underwent laparotomy within 90 minutes of admission to the ED. Emergency Department systolic blood pressure (SBP) was not available for 60/821 (7.3%) leaving 761 available for analysis. Of the 761 casualties undergoing a laparotomy within 90 minutes of arrival to the ED, 490 (64%) were injured by gunshot, 240 (31.5%) by blast, and 24 (3.2%) by blunt mechanism. (table 1)

Overall, mortality was 99/761 (13.0%); mortality for coalition troops was 26/329 (7.9%), compared to 73/432 (16.9%) non-coalition patients ($p<0.001$). Survival for all patients having laparotomy within 90 mins of arrival was 85% at the beginning of the study and 88% at the end of the study ($p=0.075$). There were no significant differences in arrival SBP however ISS significantly increased over time from 19 (IQR 9-28) in 2006 to 24 (IQR 17-34) in 2014, $p = 0.01$.

Hypotension was present on arrival at the ED in 155 military patients (20.4%). Mortality was higher in hypotensive casualties (25.8% vs 9.7%, $p<0.001$). For the cohort of patients who were hypotensive on arrival at the ED neither the average injury severity, the prehospital time, the ED arrival SBP, nor mortality changed significantly across the study period. The three-year averages for these variables at the beginning of the study period vs the end of the study period are respectively: ISS 21 (13–32) vs 32 (23-42) (Figure 1A); Prehospital time 91 (44-169) vs 92 (50-148) minutes, and SBP 82 (70-89) vs 75 (66-86) mmHg. The proportion of casualties receiving a prehospital blood transfusion increased from 3% to 43% $p = 0.017$.

The civilian MTC trauma registry contained 16 506 civilian patients injured or killed during the study period (2012-2016). 199 (1.2%) underwent laparotomy within 90 minutes of admission to the ED. ED SBP was not available for 23 patients, leaving 176 patients for analysis. Of the 176 patients undergoing laparotomy within 90 minutes, 95 (54.0%) had a penetrating mechanism of injury (table 2).

Overall mortality was 44/176 (25%). Hypotension was present on arrival at the ED in 63 (35.7%) civilian patients (compared to 20.4% of military patients, p<0.001). Mortality was higher in hypotensive patients 47.6% vs 12.4% normotensive patients (p<0.001). As in the military cohort, neither mortality, prehospital time, ED arrival SBP, nor injury severity, changed during the study period. The two-year averages for these variables at the beginning of the study period vs the end of the study period are respectively: ISS 38 (20–48) vs 27 (17-46) (Figure 1B); Prehospital time 78 (56-107) vs 95 (70-109) minutes, and SBP 65 (52-81) vs 66 (29-84) mmHg.

For both cohorts, multivariable analysis (table 3) confirms that degree of hypotension at presentation, ISS, age and female gender were each significantly associated with mortality. There was no discernible effect of patient cohort (military or civilian) on mortality once these significant variables were controlled for. Civilian patients, arriving alive, at the ED had higher in-hospital mortality compared to military casualties, but were more severely injured and more shocked on arrival than military patients.

DISCUSSION

This current study confirms the previous observation that incremental improvements in survival have been achieved in coalition military casualties from 2003 to 2012. (4) However, despite improvements in survival overall, survival for military patients undergoing laparotomy who arrived hypotensive at the ED did not significantly change between 2007 and 2014 with the mortality rate remaining stubbornly around 26%. Similarly, the mortality rate at The Royal London MTC did not change significantly between 2012-2016 with an average mortality rate of 48%. These results mirror the recent study by Harvin and co-workers and reinforce the unexpected finding that for the highest risk patients, mortality after laparotomy for trauma appears not to have improved significantly over the last many years.

The difference in 'headline' mortality of 47% for civilians and 26% for the military cohort is striking. There are obvious differences in the trauma systems, wounding mechanisms, patients and time periods from which the data were drawn. Military wounding mechanisms are typically of high energy and combat wounds have high early lethality, with most deaths occurring prehospital. (13, 14) Additionally, soldiers have modified wounding patterns (and thus outcomes) due to personal protective equipment (PPE); in this study, mortality for coalition troops undergoing laparotomy was approximately half that of non-coalition patients without modern PPE. The prehospital environment is also dramatically different between these military and civilian cohorts; for example, all soldiers receive universal training in bystander trauma first aid (“Buddy-Buddy aid”), wounds in survivors of combat injury disproportionately affect the extremities and all service members are individually equipped with tourniquets and dressings. In addition, typically, military personnel on deployment are young, generally free from co-morbidities and all undergo physical conditioning.

Despite these differences in the patient cohorts, some findings remain particularly striking; for example, the proportion of patients arriving hypotensive at the ED was higher in the civilian cohort (36%) compared to the military cohort (20%). The multiple regression analysis attempted to control for important confounders and includes measurable variables. Almost certainly, there are unmeasured confounders between the cohorts that are not accounted for in the multivariate analysis. Nonetheless, this study suggests for hypotensive patients undergoing laparotomy within 90 minutes of ED arrival, the key determinants of mortality for both cohorts are; age, injury severity, and degree of hypotension; that female gender is associated with a poor outcome in our analysis is unexplained.

Mortality within our British MTC for this group of patients (48%) is similar to the average rate of 46% published from the combined US Level 1 centers, which itself has remained unchanged across 20 years. One possible explanation for the absence of an apparent improvement in mortality in the civilian cohort is a selection bias that reserves laparotomy for the more severely injured and/or physiologically compromised. In the modern health service, patients who previously would have been managed by laparotomy may have both solid organ and penetrating injuries managed non-operatively. In both cohorts, improvements in prehospital care, with improved pre-hospital resuscitation and transport times leads to more severely injured patients arriving alive at the trauma centre than previously, in effect re-categorising those who might have been “dead on arrival” to “postoperative mortality”. (15-17) As 'hypotensive resuscitation' becomes more nuanced and pre-hospital blood transfusion is utilised, patients responsive to blood transfusion may transition from the hypotensive group to the normotensive group by arrival at ED. This circumstance could translate into non-fluid responders, with their highest mortality, remaining in the shocked group and the initial responders being assigned 'normotensive' on arrival, thus diminishing survival overall for both the hypotensive and the normotensive groups, an inversion of the Will Rogers phenomenon.(18)

As noted by Harvin et al., (8) civilian pre-hospital times were longer amongst patients who arrived hypotensive than those who were normotensive on arrival. Like Harvin, we have not investigated reasons for this. However, possible explanations include casualty entrapment or time spent on-scene for resuscitative interventions. In contrast, military pre-hospital times were almost identical between the two groups, likely indicating that the tactical situation and geography are the compelling determinants of military prehospital time.

We acknowledge this work has limitations; relying as it does on registry data and subject to the inaccuracies common to all such study designs. As a surrogate measure of accuracy of data capture between the military and civil trauma systems, we found 60/821 (7.3%) military patients did not have admission blood pressure recorded compared to 23/199 (11.5%) of the civilian patients (p=0.0595). This study can only identify trends and associations and not establish causation. Elements of the methodology are replicated from Harvin's study (10) to facilitate comparison between cohorts. However, definitions of hypotension, normotension and a cut-off of 90 minutes to laparotomy from ED arrival do not fully define our patient populations; for example: time to death starts after injury and not arbitrarily after ED admission.. A deficiency in our study is the absence of complete data on pre-hospital time; understanding of the temporal association of the injury to death and the outcomes of patients with excess mortality (such as patients with severe traumatic brain injury in addition to their abdominal injury) will enable us to better understand where the most pressing improvement challenges lie. The timings for which we do have more complete data: ED arrival to laparotomy, seem to offer opportunities for quality improvement; the time in the military setting was 25 and 35 minutes for hypotensive and non-hypotensive patients and 32 and 47 minutes respectively in the civilian cohort.

CONCLUSION

Mortality for patients requiring laparotomy who are hypotensive on arrival at ED has not changed in recent years despite what we have widely considered as advances in 'damage control resuscitation and surgery'. Coalition military providers are proud to have contributed to improvements in outcome for their patients during the large-scale conflict in Iraq and Afghanistan and there has been cross-over in learning between military and civil sectors. However, history suggests that times of relative peace can lead to a reduction in focus on military trauma care; the so-called ‘Walker Dip’. (19) Improvements are possible in all areas, from prevention and injury mitigation to decreasing prehospital times, improving pre and in-hospital resuscitation and surgery. Further improvements in pre and in-hospital data capture and further focused research are warranted.

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AUTHOR CONTRIBUTIONS

M.M., R.C., L.N. and D.B. designed the study. M.M.. R.C., L.K., K.B., N.T., and D.B., collected and analysed the data. M.M., R.C., L.N., I.S., and J.P-B and drafted the manuscript. M.M., I.S., K.B., N.T., and D.B. critically revised the manuscript. All authors agreed the final submission.

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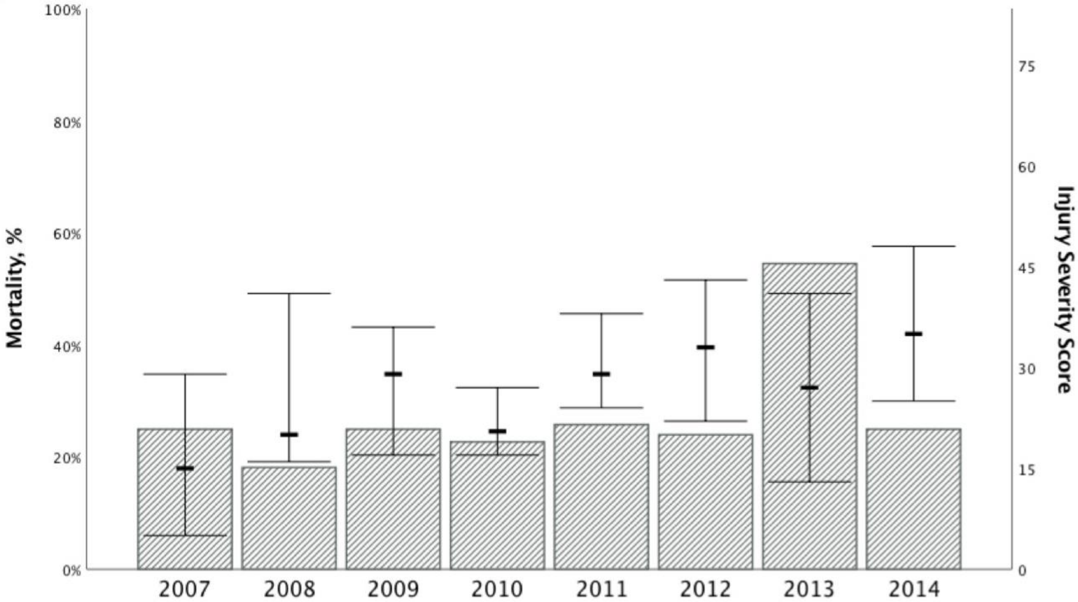
FIGURE LEGENDS

Figure 1 **A** and **B**: Mortality and Injury Severity Score in hypotensive patients undergoing laparotomy within 90 minutes from arrival in the emergency department. **A:** Military Casualties. **B:** Civilian Patients.

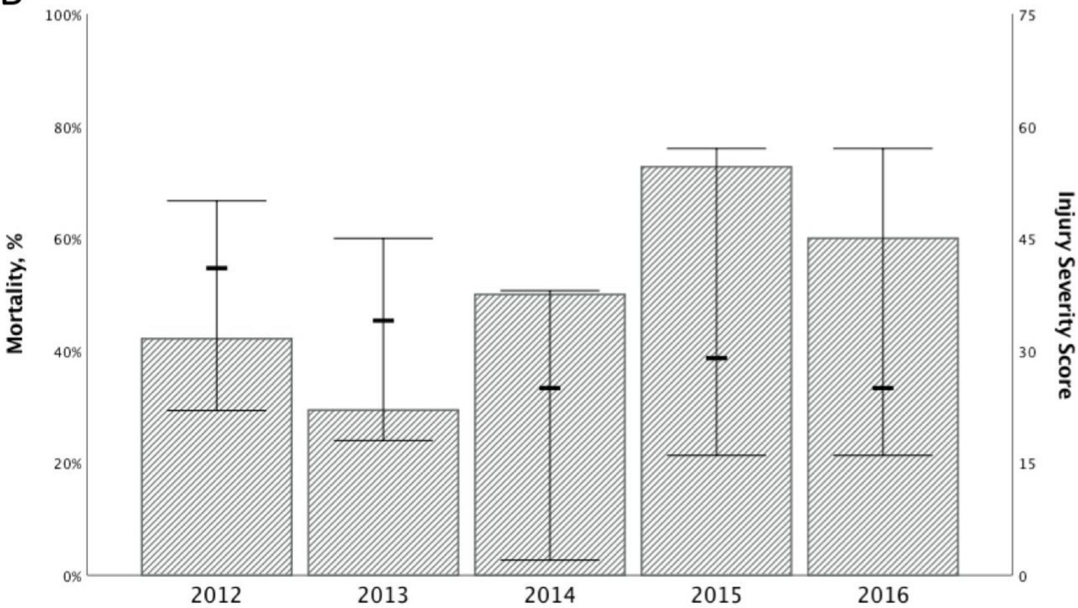
Legend: No significant trend in mortality by year in either cohort. **1A**: p = 0.193. **1B** p = 0.074. In the military cohort only one patient was available for analysis prior to 2007, these years were therefore excluded.

A



100%
80%
60%
40%
20%
0%
Mortality, %
75
60
45
30
15
0
Injury Severity Score
2007
2008
2009
2010
2011
2012
2013
2014

B



100%
80%
60%
40%
20%
0%
Mortality, %
75
60
45
30
15
0
Injury Severity Score
2012
2013
2014
2015
2016

Table 1: Military Patients undergoing laparotomy with 90 minutes

	Normotensive	Hypotensive	
	All	Survived	Died
n	606	115	40
Characteristics			
Age, years	23 (20-27)	25 (20-28)	30 (18-36)
Male gender / n (%)	592 (97.7)	33 (100)	16 (94.1)
Injury Severity Score	18 (10-29)	26 (17-33)	34 (24-43)
Mechanism of Injury			
Blast / n (%)	179 (29.5)	44 (39.3)	17 (42.5)
Penetrating / n (%)	401 (66.2)	67 (59.8)	22 (55.0)
Blunt / n (%)	22 (3.6)	1 (0.9)	1 (2.5)
Unknown or Combined / n (%)	4 (0.7)	0	0
Admission Physiology			
GCS	15 (3-15)	3 (3-15)	3 (3-10)
Heart Rate, bpm	105 (85-129)	124 (142-105)	115 (97-127)
Systolic BP, mmHg	127 (110-140)	79 (70-87)	76 (61-86)
Treatment[1]			
Pre-hospital time / minutes	68 (49-114)	65 (45-120)	66 (41 -110)
Received PH Blood / n (%)	87 (16)	33 (28.7)	17 (42.5)
Pre-hospital blood / Units / patient transfused	4 (2-4)	4 (2-4)	3 (2-7)
Total PRBC / Units	5 (1-12)	17 (9-27)	18 (12-28)
Total FFP / Units	4 (0-12)	15 (8-26)	16 (9-34)
Time to Lap / minutes	35 (20-50)	25 (13-45)	24 (14-47)
Mortality			
Overall, n (%)	59 (9.7)		40 (25.8)
Blast / n (%)	14 (8)		17 (27.9)
Penetrating / n (%)	40 (10)		22 (24.7)
Blunt / n (%)	3 (14)		1 (50.0)

[1]The denominator changes for the prehospital metrics due to the variable availability of pre-hospital data in the trauma registry Admission Lactate and Base Deficit are not routinely recorded in the JTTR database

Table 2: Civilian Patients undergoing laparotomy with 90 minutes

	Normotensive	Hypotensive	
	All	Survived	Died
n	113	33	30
Characteristics			
Age, years	27 (22-39)	29 (18-42)	36 (27-53)
Male gender / n (%)	98 (86.7)	11 (100)	3 (42.9)
Injury Severity Score	18 (9-32)	27 (19-44)	36 (25-49)
Mechanism of Injury			
Blunt / n (%)	41 (36.3)	18 (54.5)	22 (73.3)
Penetrating / n (%)	72 (63.7)	15 (45.5.3)	8 (26.7)
Admission Physiology			
GCS	15 (15-15)	14 (7-15)	3 (3-14)
Heart Rate, bpm	90 (76-111)	123 (89-141)	108 (8-125)
Systolic BP, mmHg	118 (107-135)	77 (68-83)	59 (29-67)
Lactate, mmol/L	3.5 (2.0-6.4)	7.1 (4.8-11.7)	9.9 (6.9-15.3)
Base Deficit, mmol/L	3.4 (1.2-7.6)	8.7 (2.4-14.0)	17.6 (7.9-23.6)
Treatment[1]			
Pre-hospital time / minutes	67 (51-96)	70 (49-93)	94 (71-127)
Received PH Blood / n (%)	17 (38)	11 (78.6)	7 (63.6)
Pre-hospital blood / Units / patient transfused	2 (1-4)	2 (1-4)	4 (1-6)
24HR PRBC / Units	6 (3-11)	8 (5-11)	16 (12-36)
24HR FFP / Units	6 (4-9)	8 (4-9)	14 (8-28)
Time to Lap / minutes	47 (35-62)	40 (26-55)	28 (21-49)
Mortality and Length of Stay			
Overall Mortality, n (%)	14 (12.4)		30 (47.6)
Penetrating Mortality / n (%)	3 (4.2)		8 (34.8)
Blunt Mortality/ n (%)	11 (26.8)		22 (55.0)
Length of Stay / Days	7 (5-19)	21 (7-41)	2 (0-29)

[1]The denominator changes for the prehospital metrics due to the variable availability of pre-hospital data in the trauma registry

Table 3: Multiple regression model for hypotensive laparotomy patients

	Univariable Model	Multivariable Model	
Variable	**P-value**	**OR (95% CI)**	**p value**
Age	<0.001	1.04 (1.02, 1.07)	0.003
Gender (female)	<0.001	8.11 (1.74, 37.74)	0.008
ISS	<0.001	1.03 (1.01, 1.06)	0.005
SBP	<0.001	0.94 (0.92, 0.97)	<0.001
Cohort (military)	0.002		
Year in cohort	0.682		
GCS	0.006		
Heart Rate	0.002		
Mechanism of Injury			
Civilian Penetrating	0.151		
Military Penetrating	0.334		
Blast	0.537		
Blunt	0.127		
PreHospital Time	0.578		
Respiratory Rare	0.103		
Severe Traumatic Brain Injury	0.045		
Time to Operation, minutes	0.352		
Units of Prehospital Blood	0.023		

Legend: ISS, Injury Severity Score; SBP, Systolic Blood Pressure; GCS, Glasgow Coma Score. Year in cohort is defined as the year from the start of cohort data collection period. Severe traumatic brain injury is defined as an Abbreviated Injury Severity Score Head ≥ 4