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The effect of trauma center verification level on traumatic brain injury outcome after implementation of the Orange Book

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ABSTRACT

Background: Previous literature demonstrates mortality discrepancies at Level II vs. Level I centers in patients with isolated Traumatic Brain Injury (TBI). Our hypothesis is that the implementation of the 2014 version of the resources manual ("the Orange Book") is associated with an elimination of this outcome disparity.

Methods: Utilizing the Trauma Quality Program Participant Use File for 2017, we compared TBI outcomes at ACS Level I vs. Level II centers.

Results: 39,764 records met inclusion criteria where 25,382 (63.8%) were admitted to a Level I center. Level I patients were younger (56.4 vs. 59.1 years, $p < 0.001$) and less likely to have been injured in a single level fall (39.5% vs. 45.5%, $p < 0.001$). The incidence of severe TBI (11.3% vs. 10.3%, $p < 0.001$) was more common. Adjusted mortality at a Level II vs. Level I center were similar [7.8% vs. 8.4%, 0.669].

Conclusions: Implementation of 2014 version of the ACS resources manual is associated with improved TBI associated mortality in ACS Level II centers relative to their Level I counterparts.

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Introduction

Since 1976, the American College of Surgeons-Committee on trauma (ACS-COT) has outlined appropriate resources for ideal trauma care. The document, initially entitled "Optimal Hospital Resources for the Care of the Injured Patient", became known as "Resources for the Optimal Care of the Injured Patient" (or the "Resources manual") to emphasize the growing importance of a systems approach.¹ This document defines escalating resources used to verify trauma centers into a tiered classification paradigm. Therefore, admission to a level I center would be expected to yield superior outcomes for complex wounding such as Traumatic Brain Injury (TBI) and, indeed, this was demonstrated by previous investigations.^{2,3} The latest version of the Resources manual, the "Orange Book", was implemented in 2014. In this revision, "level I and II criteria were reviewed and revised to ensure that both types of trauma centers are available to provide high quality definitive

care."¹ Essentially all clinical functionality of the level II center was expected to be equivalent to the level I. It should follow that this would result in similar outcomes in TBI though there is sparse literature to support this. Our hypothesis is that the previously described mortality disparities in TBI patients between ACS verified Level I and II centers are reduced or eliminated after implementation of the "the Orange Book".

Materials and methods

Utilizing the 2017 Trauma Quality Program Participant Use File (TQP-PUF), we identified adult patients (age 16–90 years) directly admitted to an ACS verified level I or level II center with an isolated TBI. We used this dataset, encompassing a three year delay from implementation of the Orange Book, to allow for more full integration of the new requirements across submitting trauma centers. Isolated TBI was identified by a Head Abbreviated Injury Score (AIS) ≥ 3 with an AIS score for all other body regions < 3 . We extracted all pertinent demographic and injury variables. This included but was not limited to gender, race, mechanism of injury (E codes), Systolic blood pressure (SBP) on admission, Glasgow Coma Scale (GCS) score, Injury Severity Score (ISS) and the presence

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of chronic conditions (alcohol abuse disorder, the use of anticoagulants, CVA, dementia, diabetes, CHF, HTN, psychiatric disorders and substance abuse). The impact of chronic conditions was grouped into a single variable consisting of ≥ 2 diagnoses (“multiple chronic conditions”). Outcome variables include ICU/hospital lengths of stay (ICU/HOSP LOS), procedures performed, complications (alcohol withdrawal, cardiac arrest, CAUTI, CLABSI, DVT, VTE, renal dysfunction, unplanned return to ICU, sepsis, and VAP) and mortality. Hospital complications were analyzed in aggregate.

Continuous variables were converted to dichotomous variables to include age (>55 years), Emergency Department hypotension (ED Hypo, admission SBP < 90 mmHg), hypoxia (O_2 sat $< 93\%$), severe TBI (GCS < 9), and severe injury (ISS > 15). All GCS measurements refer to the best GCS at 24 h to maintain concurrence with accepted stratification of TBI severity. Demographic and injury variables were compared between the groups admitted to a Level I versus a Level II center. Similarly, variables were studied for their association with mortality. Univariate analysis was performed using students *t*-test or ANOVA for continuous variables and χ^2 for dichotomous variables. All variables with a *p*-value of <0.05 on univariate analysis were then entered into forward stepwise logistic regression to determine adjusted mortality outcomes with admission to a level II center being added into the model. SPSS v 21, Chicago, IL was used for statistical analysis. Comparisons were statistically significant with a *p*-value <0.05 .

Results

There were 39,764 patients meeting inclusion criteria. The group was generally male [25,895 (65.1%)] and white [30,070 (75.6%)]. Most sustained injuries in a same level fall (SLF) [16,558 (41.6%)]. The group was severely injured [mean ISS was 16.2 (± 6.9)]. Severe (GCS 3–8), moderate (GCS 9–12) and mild (GCS 13–15) TBI were present in 4348 (10.9%), 2367 (6.0%) and 33,049 (83.1%) of admissions, respectively. Only 527 (1.3%) presented with ED Hypo and 2330 (5.9%) were hypoxic. Most were admitted to the ICU after ED evaluation [22,822 (57.4%)]. Intracranial pressure monitoring (Intraventricular or parenchymal device) was utilized in 2390 (6%) of cases while craniotomy was performed in 3870 (9.7%). Mean ICU and hospital LOS were 4.8 (± 5.9) and 6.3 (± 10.2) days, respectively. There were 3249 (8.2%) deaths (Table 1).

Comparison of Level I versus Level II admissions are depicted in Table 2. There were 25,382 (63.8%) admissions to a Level I and 14,382 (36.2%) admission to a Level II center. Level I admissions were more likely male [16,838 (66.3%) vs. 9057 (63%), <0.001], younger [56.4 (± 21.5) vs. 59.1 (± 21.4) years, <0.001], non-white [18,707 (73.7%) vs. 11,363 (79%), <0.001] and less likely sustained injuries in a SLF [10,019 (39.5%) vs. 6540 (45.5%), <0.001] versus a penetrating mechanism [1002 (3.9%) vs. 349 (2.4%), <0.001]. Additionally, there was a higher incidence of severe injury (ISS > 15) [13,070 (51.1%) vs. 6782 (47.2%), <0.001] and severe TBI [2873 (11.3%) vs. 1476 (10.3%), <0.001] at level I centers though the incidence of multiple comorbidities was similar [4941 (19.5%) vs. 2853 (19.8%), 0.371]. There was a similar incidence of immediate operation [1538 (6.1%) vs. 867 (6%), 0.685] but more underwent monitoring device placement [1630 (6.4%) vs. 760 (5.3%), <0.001] and craniotomy [2614 (10.3%) vs. 1265 (8.7%), <0.001] at a Level I center. Overall LOS [6.7 (± 11) vs. 6.6 (± 8.6) days, <0.001] and ICU LOS [5.0 (± 6.1) vs. 4.6 (± 5.5) days, <0.001] were somewhat longer at Level I centers. Level I center admits were more likely to a larger (401–600 beds) [8751 (34.5%) vs. 2175 (15.1%), <0.001] University teaching facility [18,537 (73.0%) vs. 1181 (12.6%), <0.001] (not shown in table). Unadjusted mortality trended higher at Level I centers [2126 (8.4%) vs. 1123 (7.8%), 0.047].

Comparison of patients that died vs. survived (Table 3) show

Table 1

Demographic variables for the Study Population.

Variable	n or mean (% or sd.)
Study patients	39,764
Admitted to Level I	25,382 (63.8)
Gender (male)	25,895 (65.1)
Mean Age (years)	57.4 (± 21.5)
Asian-Pacific Islander	4076 (10.3)
Black	1333 (3.3)
White	30,070 (75.6)
Other	4285 (10.8)
Mechanism	
Fall from height	6035 (15.2)
Same level fall	16,558 (41.6)
Motorcycle	1614 (4.0)
Motor vehicle	5138 (12.9)
Pedestrian/bicycle	3003 (7.6)
Penetrating	1351 (3.4)
Sports/recreation	1334 (3.4)
Other blunt	4731 (11.9)
Injury severity	
Mean ISS	16.2 (± 6.9)
Severe TBI (GCS 3–8)	4348 (10.9)
Moderate TBI (GCS 9–12)	2367 (6.0)
Mild TBI (GCS 13–15)	33,049 (83.1)
Admission Hypotension (SBP < 90 mmHg)	527 (1.3)
Admission Hypoxia (O_2 Sat $< 93\%$)	2330 (5.9)
Co-morbidities	
Alcohol use disorder	4412 (11.1)
Anticoagulation use	4991 (12.6)
COPD	2363 (5.9)
Diabetes	6578 (16.5)
Hypertension	16,311 (41.0)
Substance abuse	2855 (7.2)
Multiple co-morbidities (≥ 3 diagnoses)	7794 (19.6)
Treatment	
ED to ICU	22,822 (57.4)
ED to OR	2395 (6.0)
Craniotomy	3870 (9.7)
Monitor	2390 (6.0)
Outcomes	
ICU LOS (days)	4.9 (± 5.9)
Hospital LOS (days)	6.3 (± 10.2)
Home (self-care)	20,338 (51.1)
Mortality	3249 (8.2)

Data are expressed as raw numbers, percentages, and means with standard deviations.

that males [2260 (69.6%) vs. 23,635 (64.7%), <0.001], patients with penetrating injury [382 (11.8%) vs. 969 (2.7%), <0.001] and older patients [mean age 62.3 (± 20.6) vs. 56.9 (± 21.6), <0.001] were more likely to die. Patients with severe TBI were at marked risk of death [2081 (64.1%) vs. 2267 (6.2%), <0.001] as were more severely injured patients [mean ISS 24.2 (± 7.9) vs. 15.4 (± 6.3), <0.001] Of note, there was no significant association with hospital size (>600 beds) [1236 (38%) vs. 13,806 (37.8%), 0.793] or teaching status (University) [1708 (52.6%) vs. 18,640 (51%), 0.096]. There was a small mortality increase at level I centers [2126 (65.4%) vs. 23,256 (63.7%), 0.047].

On logistic regression (Table 4: adjusting for TBI severity, ISS, age, gender, race, admission hypotension and hypoxia, the presence of comorbidities, trauma type, primary payor source, and admission to a Level II versus Level I trauma center), the presence of severe TBI, ED hypotension, ISS > 15 , age > 55 years, hypoxemia in the ED and the presence of multiple co-morbidities on admission were associated with death. However, the adjusted risk of mortality was similar at a level II compared to a level I trauma center [0.972 (0.854–1.103), 0.669].

Table 2
Comparison of admissions to level I versus level II trauma centers.

Variable	Level I (n = 25,382)	Level II (n = 14,382)	OR/mean diff. (95% CI), p-value
Gender (male)	16,838 (66.3)	9057 (63.0)	1.159 (1.110–1.209), <0.001
Mean age (years)	56.4 (±21.5)	59.1 (±21.4)	–2.775 (–3.195, –2.315), <0.001
Asian-Pacific Islander	946 (3.7)	387 (2.7)	<0.001
Black	3048 (12.0)	1028 (7.1)	
White	18,707 (73.7)	11,363 (79.0)	
Other	2681 (10.6)	1604 (11.2)	
Mechanism			
Fall from height	3871 (15.3)	2164 (15.0)	<0.001
Same level fall	10,019 (39.5)	6540 (45.5)	
Motorcycle	1074 (4.2)	540 (3.8)	
Motor vehicle	3292 (13.0)	1846 (12.8)	
Pedestrian/bicycle	2026 (8.0)	977 (6.8)	
Penetrating	1002 (3.9)	349 (2.4)	
Sports/recreation	802 (3.2)	532 (3.7)	
Other blunt	3297 (13.0)	1434 (10.0)	
Injury Severity			
Mean ISS	16.6 (±6.7)	15.4 (±7.1)	1.120 (0.980–1.260), <0.001
Severe TBI (GCS 3–8)	2873 (11.3)	1476 (10.3)	1.116 (1.044–1.192), <0.001
Moderate TBI (GCS 9–12)	1620 (6.4)	747 (5.2)	1.244 (1.138–1.361), <0.001
Mild (GCS 13–15)	20,890 (82.3)	12,159 (84.5)	0.850 (0.804–0.899), <0.001
Admission Hypotension	342 (1.3)	185 (1.3)	1.048 (0.875–1.255), 0.609
Admission Hypoxia	1420 (5.6)	910 (6.3)	0.977 (0.805–0.956), 0.003
Co-morbidities			
Alcohol use disorder	2893 (11.4)	1519 (10.6)	1.089 (1.020–1.163), 0.011
Anticoagulation use	2865 (11.3)	2126 (14.8)	0.733 (0.691–0.779), <0.001
COPD	1447 (5.7)	916 (6.4)	0.889 (0.816–0.968), 0.007
Diabetes	4146 (16.3)	2432 (16.9)	0.959 (0.908–1.013), 0.138
Hypertension	10,103 (39.8)	6208 (43.2)	0.871 (0.835–0.908), <0.001
Substance abuse	1990 (7.8)	865 (6.0)	1.329 (1.224–1.44), <0.001
Multiple co-morbidities	4941 (19.5)	2853 (19.8)	0.977 (0.928–1.028), 0.371
Treatment			
ED to ICU	14,331 (56.5)	8491 (59.0)	0.990 (0.863–0.938), <0.001
ED to OR	1538 (6.1)	857 (6.0)	1.018 (0.934–1.110), 0.685
Craniotomy	2614 (10.3)	1256 (8.7)	1.200 (1.118–1.288), <0.001
Monitor	1630 (6.4)	760 (5.3)	1.230 (1.126–1.344), <0.001
Outcomes			
ICU LOS (days)	5.1 (±6.1)	4.6 (±5.5)	0.487 (0.338–0.635), <0.001
Hospital LOS (days)	6.7 (±11.0)	5.6 (±8.6)	1.108 (0.896–1.319), <0.001
Home (self care)	13,105 (51.6)	7233 (50.3)	1.055 (1.013–1.099), 0.010
Mortality	2126 (8.4)	1123 (7.8)	1.079 (1.001–1.164), 0.047

Discussion

Investment in trauma center designation with ACS-COT Level I or II verification is significant.¹ Most costs relate to maintenance of high-level services that are incrementally robust.⁴ Studies have confirmed that level I centers, with the benefit of more resources, demonstrate improved outcomes in overall admissions^{5,6} in the severely injured (ISS > 15),⁷ for patients with solid organ injuries,⁸ in the presence of hemorrhagic shock,⁹ after ventilator associated pneumonia,¹⁰ and in severe TBI.² Despite this, other data supports equivalence^{11–13} or even superior,¹⁴ outcomes at level II centers.

The ACS-COT has assisted trauma center verification guided by the document “Resources for the Optimal Care of the Injured Patient”.¹ The most recent Resources manual, implemented in 2014, standardized the requirements of a Level I versus Level II center while enhancing the performance improvement and patient safety sections (chapter 16) and mandating participation in risk adjusted data submission.^{4,15} Generally, previous studies showing outcome discrepancies between Level I and Level II centers utilized data gathered prior to this most recent update. Our data shows that implementation of the most recent Resources manual is associated with mortality improvement in isolated TBI in level II centers relative to their level I counterparts.

Many of the enhancements relate to Level I and II centers and require stringent monitoring of patient outcomes and audit filters. Notable resourcing changes are, registrar training and staffing

minimums, minimum criteria for highest level activations, injury prevention positions and up-resourcing of anesthesia and radiology support. Of pertinence, Neurotrauma related changes include criteria for immediate neurosurgeon bedside response, more specific guidelines for back-up and neurotrauma diversion, and PIPS review of other TBI outcomes. It is difficult to determine the specific etiologies of demonstrated improvements in neurotrauma care yet more robust resourcing overall is supported by conjecture and, most importantly, data.^{16,17} The Orange Book is a significant enhancement to the trauma system overall and, hence, patient care by making higher level resources more widely available and recommend adoption to trauma systems not already utilizing ACS verification or other similar leveling of resources.

Optimal outcome after TBI, because of its prototypical complexity, is dependent on essentially all aspects of a trauma center's high intensity resources. Our findings support this association and suggest that the resource commitment related to the new Level II requirements result in improved outcomes in this population. Use of the most recent version of the TQP-PUF improves the veracity of our findings since there is little risk of variability associated with smaller studies based on regional or local data. Further, our comparison to previous studies is not confounded by use of a different data collection process since previous studies also utilized the same submission program (i.e. “The National Trauma Data Bank Research dataset” as it was known prior to 2017's “TQP-PUF”).

Our study suffers from its basic retrospective design and, thus,

Table 3
Comparison of deaths versus survivors after isolated TBI.

Variable	Deaths (n = 3249)	Survivors (n = 36,515)	OR/mean diff. (96% CI), p-value
Gender (male)	2260 (69.6)	23,635 (64.7)	1.245 (1.152–1.346), <0.001
Mean age (years)	62.3 (±20.6)	56.9 (±21.6)	5.367 (4.596–6.138), <0.001
Asian-Pacific Islander	142 (10.7)	1191 (8.1)	<0.002
Black	310 (9.5)	3766 (10.3)	
White	2470 (76.0)	27,600 (75.6)	
Other	327 (10.1)	3958 (10.8)	
Mechanism			
Fall from height	555 (17.1)	5480 (15.0)	<0.001
Same level fall	1445 (44.5)	15,114 (41.4)	
MVT (Motorcycle)	97 (3.4)	1517 (4.2)	
MVT (Motor Vehicle)	244 (7.5)	4894 (13.4)	
Pedestrian/bicycle	252 (7.8)	2751 (7.5)	
Penetrating	382 (11.8)	969 (2.7)	
Sports/recreation	47 (1.4)	1287 (3.5)	
Other blunt	227 (7.0)	4504 (12.3)	
Injury Severity			
Mean ISS	24.2 (±7.9)	15.4 (±6.3)	8.724 (8.492–8.955), <0.001
Severe TBI (GCS 3–8)	2081 (64.1)	2267 (6.2)	26.916 (24.764–29.255), <0.001
Admission Hypotension	215 (6.6)	312 (0.9)	8.223 (6.884–9.821), <0.001
Admission Hypoxia	378 (11.6)	1952 (5.3)	2.331 (2.075–2.619), <0.001
Co-morbidities			
Alcohol use disorder	335 (10.3)	4077 (11.2)	0.915 (0.813–1.029), 0.137
Anticoagulation use	622 (19.1)	4369 (12.0)	1.742 (1.588–1.912), <0.001
COPD	243 (7.3)	2120 (5.8)	1.312 (1.143–1.505), <0.001
Diabetes	653 (20.1)	5925 (16.2)	1.299 (1.187–1.421), <0.001
Hypertension	1376 (42.4)	14,935 (40.9)	1.062 (0.987–1.142), 0.107
Substance abuse	169 (5.2)	2686 (7.4)	0.691 (0.589–0.811), <0.001
Multiple co-morbidities	755 (23.2)	7039 (16.3)	1.268 (1.164–1.381), <0.001
Hospital type			
Size > 600 vs < 600 beds	1236 (38.0)	13,806 (37.8)	1.010 (0.938–1.087), 0.793
Univ. teaching vs comm. teaching + non-teaching	1708 (52.6)	18,640 (51.0)	1.063 (0.989–1.142), 0.096
Level I vs. Level II	2126 (65.4)	23,256 (63.7)	1.079 (1.001–1.164), 0.047

we are unable to study more subtle differences between Level I and II centers not reflected in the dataset. However, one would expect that similar resourcing for this patient population would result in similar outcome. In addition, with a study of this population size, statistical significance does not always equate to clinical significance. However, should variables show no statistical significance relevant to an outcome in a study population of this size, we can confidently say that they are indeed equivalent. Further, our definition of TBI severities are not entirely consistent with the formal descriptions that include duration of unconsciousness, CT scan findings and duration of alteration in consciousness.¹⁸ Despite this, we believe our stratification of TBI severity is valid since we do utilize the best GCS at 24 h (not at admission) which is consistent with the formal definitions of TBI severity stratification.¹⁸ It is important to remember that our findings apply only to ACS Level I and Level II TCs. We would further caution that submitted data to the 2017 TQP-PUF may, or may not, have been after the submitting trauma center's adoption of the Orange Book. However, beginning in 2015, ACS verified trauma centers were required to comply. Therefore, we feel confident that, by 2017, the vast majority of ACS

Table 4
Adjusted mortality outcomes for isolated TBI.

TBI severity	6.052 (5.738–6.383), <0.001
ED Hypo	4.019 (3.156–5.114), <0.001
ISS >15	3.678 (3.278–4.136), <0.001
Age >55 years	3.447 (3.061–3.880), <0.001
Hypoxemia in the ED (O ₂ sat<93%)	1.552 (1.340–1.798), <0.001
Multiple Co-morbidities (≥2)	1.472 (1.319–1.644) <0.001
Admission to Level II center	0.972 (0.854–1.106), 0.669
Other variables entered into forward stepwise regression: Admission to a Level II versus Level I TC, Male gender, race, mechanism, ED Hypotension (SBP < 90 mmHg), mechanism and primary payor source.	

trauma centers were following the latest Resources manual to achieve verification. Another caveat is that not all designating authorities utilize ACS-COT verification, instead, opting for state or local verification requirements and processes and therefore, we excluded non ACS-COT verified TC entries. We do not know if our main findings would have simply happened de-novo and this is common with essentially all retrospective studies. We would advocate, however, that our findings relate to mandated improvements for Level II centers being logically followed by outcome improvements in TBI patients. Despite these shortcomings, we demonstrate improvement in mortality in patients with isolated TBI at ACS verified Level II centers relative to Level I centers after implementation of the latest ACS-COT guidelines.

Of note, hospital size and university affiliation were not associated with mortality. This is shown previously,¹⁰ though findings vary.¹⁹ Our study is impactful since it shows that Level II centers can be considered clinically equivalent to a Level I for system planning purposes as it relates to Neurotrauma. Mandating equivalency at a Level I and Level II trauma centers may, counterintuitively, preserve the identity of the Level I since leaders of publicly funded health systems may be more reluctant to pursue elevated status knowing that outcomes would be unchanged despite greater costs. Alternatively, Level I status could enhance institutional prestige of a Level II center and thus commercial attractiveness, of a public or private organization. With this consideration, Level II center leadership may seek Level I verification after assessing for incremental costs that may be small compared to the already significant investment to comply with the new level II verification requirements.

Conclusion

Implementation of the “Orange Book”, the 2014 version of the document *Resources for the Optimal Care of the Injured Patient*, is

associated with improved outcomes in patients with isolated TBI at ACS verified Level II trauma centers relative to their Level I counterparts. This has impact on trauma systems design, hospital leadership decision making to achieve Level I versus Level II status and the delivery of Neurotrauma care. Further study will include examination of systems where trauma center verification and designation are not based on ACS-COT methodology but rather on state and local authority.

Declaration of competing interest

All authors declare no conflicts of interest.

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