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A METRIC OF OUR OWN: FAILURE TO RESCUE AFTER TRAUMA

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Abstract

Background—Failure to rescue (FTR) is defined as death after an adverse event. The original metric was derived in elective surgical populations and reclassifies deaths not preceded by recorded adverse events as FTR cases under the assumption these deaths resulted from missed adverse events. This approach lacks face validity in trauma because patients often die without adverse events as a direct result of injury. Another common approach simply excludes deaths without recorded adverse events, but this approach reduces the reliability of the FTR metric. We hypothesized that a hybrid metric excluding expected deaths but otherwise including patients without recorded adverse events in FTR analysis would improve face validity and reliability relative to existing methods.

Methods—Using 3 years of single-state adult trauma registry data from 30 trauma centers, we constructed 3 FTR metrics: 1.) Excluding deaths not preceded by adverse events (FTR-E), 2.) Reclassifying deaths not preceded by adverse events (FTR-R), and 2.) Including deaths not preceded by adverse events in FTR analysis except those with predicted mortality >50% (FTR-T). Mortality, adverse event, and FTR rates were calculated under each method, and reliability was tested using Spearman's correlation for split-sample center rankings.

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Author Contributions

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Results—A total of 89,780 patients were included (median age 57 (IQR 26–73), 85% Caucasian, 59% male, 92% blunt, median ISS 9 (IQR5–14)). FTR rates varied by metric (FTR-E: 11.2%; FTR-R 31.2%; FTR-T 21.4%)), as did the proportion of deaths preceded by adverse events (FTR-E 28%; FTR-R: 100%; FTR-T: 60%). Spit-sample reliability was higher FTR-T than FTR-E (rho=0.59 vs) (rho=0.27, p<0.001).

Conclusions—A trauma-specific FTR metric increases face validity and reliability relative to other FTR methods which may be employed in trauma populations. Future trauma outcomes studies examining FTR rates should use a metric designed for this cohort.

Level of Evidence—Level III

Keywords

Failure-to-rescue; metrics; outcomes

Background

The Failure to Rescue (FTR) rate is defined as the conditional probability of death after an adverse event(1). The FTR metric enjoys several favorable properties that make it appealing for use in healthcare outcomes research. First, unlike adverse event rates, FTR has been demonstrated to be associated with mortality rates across a diverse range of surgical patient populations (2–4). Second, FTR rates are more strongly associated with institutional factors such as nurse-to-bed ratios and board certification rates for practitioners than are adverse event rates (5, 6). Unlike patient characteristics that are largely fixed, these institutional characteristics are subject to modification, thus suggesting a strategy to reduce center-level mortality.

Although initially described nearly 25 years ago, the FTR metric has seen a resurgence in popularity. A recent literature search reveals that the number of publications on this topic has trended up over the past 10 years, from 5 in 2004 to 72 in 2015. While the FTR metric was originally derived to analyze the elective surgical population, some of this new literature applies the metric to populations which do not share the characteristics of that population. Extending theory from one population to another occurs commonly in outcomes research but often without intervening steps to demonstrate the validity of this approach. For instance, although elements of the Donabedian model of health care quality (in which improvements in structures and processes of care result in improvements in outcomes (7)) have been utilized in trauma care since at least 1976 (8, 9), it was not until 2015 that Moore et al demonstrated this framework was valid in trauma populations (10).

The use of FTR in patients with emergent conditions has not been validated and there are conceptual reasons why application of the original metric may not be straightforward. In elective surgical populations, the majority of deaths occur following a recorded adverse event and thus the *precedence* rate (proportion of deaths *preceded* by adverse events) approaches 100%. However, there remains a subset of deaths that appear to have occurred with no recorded antecedent adverse event (*non-precedented* deaths) that represents a methodological challenge to address. In the original iteration of the FTR metric by Silber et

al., any deaths not preceded by recorded adverse events were re-classified as FTR cases under the reasonable assumption that these deaths resulted from unrecorded adverse events.

In the literature applying FTR to trauma, a second approach that has been employed is exclusion of non-precedented deaths from consideration in FTR rates. This is similar to the approach that has been adopted by the Agency for Healthcare Research and Quality's (AHRQ) FTR metric (11), under which patients who die without experiencing a specific subset of major adverse events are excluded from FTR calculations (12, 13). Excluding patients who die without recorded preceding adverse events is a reasonable consideration in the trauma population because unlike in elective surgical populations, some patients will die as a direct result of injury and not secondary to adverse events. Reclassifying these deaths as FTR events would increase the apparent FTR rate at centers caring for disproportionately severely injured patients. Since the intention of the FTR metric should be to measure death rates in patients where rescue is possible, reclassification lacks face validity in the trauma population.

However, simple exclusion of non-precedented deaths also proposes challenges to validity. First, unlike in elective surgical populations where the number of non-precedented deaths is expected to be low, the number of non-precedented deaths in trauma populations is at best 50% (14). Excluding these deaths means the majority of deaths will be excluded from FTR analysis. Since the denominator of the FTR rate is the number of patients in whom adverse events occurred, under-reporting of adverse events will result in result in an apparent decrease in the FTR rate. Given the low precedence rate in trauma populations, underreporting of adverse events could result in apparent FTR rates that are less than half of the actual rate. Additionally, as under-reporting of adverse events is a known issue in national trauma datasets (15, 16), attempting to benchmark trauma centers using simple exclusion of non-precedented deaths may misclassify some centers. Finally, using FTR metrics which capture fewer deaths has been shown to reduce the reliability of the metric in elective surgical populations, exclusion of non-precedented deaths would be expected to degrade the reliability of FTR in trauma populations.

We set out to develop an FTR metric appropriate for trauma which minimizes the limitations of methods such as simple exclusion and reclassification in this population. We hypothesized that a hybrid metric excluding non-precedented expected deaths (as defined by mortality prediction models) but thereafter including all other deaths in FTR analysis would improve split-sample reliability relative to simple exclusion of these cases.

To understand the variation in FTR estimates generated by each of these approaches, we also set out to describe the FTR rates at all level I & II trauma centers in Pennsylvania using the approach of simple exclusion of non-precedented deaths (exclusion, FTR-E), the original FTR approach (reclassification, FTR-R), and our novel hybrid approach (FTR for trauma, FTR-T).

Methods

This retrospective review was conducted in accordance with the ethical standards of the Perelman School of Medicine at the University of Pennsylvania and was approved by the Institutional Review Board.

We performed a retrospective cohort study utilizing data submitted to the Pennsylvania Trauma Outcomes Study (PTOS) from 2011–2014, a statewide prospectively collected registry curated by the Pennsylvania Trauma Systems Foundation (PTSF). Because the PTSF is responsible for accreditation of all trauma centers in the state, submission of data to PTOS is mandatory and centers are strongly incentivized to submit complete and accurate data. This data is subject to range and missingness checks at the central level, and charts are re-abstracted during site visits to ensure inter-rater reliability. Of note, patients who are dead on arrival but are not declared dead until they reach the trauma center are included in the PTOS registry. Accordingly, rates of missing data are quite low (<0.1% for adverse events, age, sex, <1% for Injury Severity Score (ISS), <10% for TRISS predicted probability of survival, race). This study included only data submitted by Level I and Level II trauma centers (n=30 for study period) and was limited to subjects age 18. Patients with a mechanism of injury of burns and those presenting to pediatric trauma centers were excluded (n=3 centers). The data were inspected for missingness; because rates were low and the intention of this work was not to directly compare centers, patients with unrecorded revised trauma scores (RTS) or ISS scores were excluded from the cohort. For the purpose of this study, an adverse event was defined as any PTOS-defined occurrence (available online at http://www.ptsf.org/upload/2015_PTOS_Manual_FINAL_Updated_4-3-2015.doc). The failure to rescue rate was defined as the proportion of deaths in the subset of patients sustaining an adverse event, while the precedence rate was defined as the proportion of deaths preceded by any adverse event.

Demographic, physiologic, and injury data of the cohort were summarized using basic statistics. First, we calculated the FTR rate using the method that has been most commonly employed in the trauma literature to date, in which deaths that occur without preceding adverse events are simply *excluded* when calculating the FTR rate (FTR-E; Figure 1A). Next, we calculated the FTR rate using the methodology designed for use in the elective surgery population described originally by Silber et al: all deaths not preceded by adverse events were assumed to represent unrecorded adverse events and thus were *reclassified* in the FTR rate (FTR-R; Figure 1B).

We then defined an FTR metric for *trauma* (FTR-T) to account for differences between elective surgical cohorts and trauma cohorts while at the same time including as many deaths as possible to generate optimal precedence rates (Figure 1C). To do this, we developed a logistic regression model to predict the probability of mortality for each patient in the cohort based on clinical and demographic risk factors. Factors found to be significant at p < 0.2 in univariate analyses on mortality were entered into a multivariate logistic regression. Evidence of interaction between RTS and ISS was tested using likelihood ratio tests. The discrimination of the model was tested using Receiver Operator Characteristic (ROC) curves, while model calibration was examined using the Hosmer-Lemeshow test as well as

visual inspection of observed to expected events across deciles of predicted mortality risk. Performance of the model throughout the cohort was examined using 10-fold cross-validation. We used the predicted probability of mortality as a threshold for reclassifying unprecedented deaths as FTR deaths as in FTR-R. Those deaths that did not meet the threshold for reclassification were excluded, as in FTR-E. To examine the performance of this metric across a variety of mortality thresholds, a sensitivity analysis was performed for by varying the exclusion threshold for predicted probability of death from 0-100 in 10% intervals and then calculating the adverse event, FTR-T, and precedence for each mortality threshold.

To examine the reliability of the three calculated FTR metrics, we performed a split-sample reliability analysis in which the patients from each trauma center were randomly divided into two groups. Centers were then ranked by each of the FTR metrics using each half of the split sample and the correlation between the rankings in the split sample was measured using Spearman's rho.

Data for this work were provided by the Pennsylvania Trauma Systems Foundation (Mechanicsburg, PA) which specifically disclaims responsibility for any analyses, interpretations, or conclusions presented herein.

Results

In total, 118,696 patients were considered for analysis (see Figure 2 for flow diagram of included and excluded patients) of which 89,780 met inclusion criteria with no exclusion criteria (Figure 2). The median age was 49 (IQR 26–73) years, 82% were Caucasian, 60% were male, 87% sustained blunt, and the median ISS was 9 (IQR4–13)) (Table 1). In total, 9,634 (10.7%) sustained an adverse event, and 3889 (4.3%) died. Of those who died, 1,080 were recorded as having a preceding adverse event for a cohort precedence rate of 27.8%. After excluding centers with < 500 patients, 27 level 1 & 2 trauma centers remained in the cohort.

Excluding deaths without adverse events to calculate the FTR-E, adverse events occurred in 9,634/89,780 (10.7%) patients, of whom 1,080/9634 died, for an overall FTR-E rate of 11.2%. In this method, the final precedence rate was equal to the native precedence rate of 27.8%, indicating that this approach excluded over 2/3 of deaths from analysis.

Reclassifying deaths that occurred without preceding adverse events as FTR cases to calculate the FTR-R rate, adverse events (including deaths in the dataset recorded as having no adverse events now reclassified as having an adverse event) now occurred in 12,443/89,780 (13.9%), of whom 3,889/8,554 died for an overall FTR-R rate of 31.3%. After reclassification of deaths not preceded by adverse events as FTR cases, the final precedence rate was 100%, indicating that approach included all deaths in FTR analysis.

To calculate the FTR-T rate, we first developed a multivariable logistic regression model on mortality. The final bootstrapped model included ISS, age, injury mechanism (blunt vs. penetrating), whether or not the patient underwent operation, maximum Abbreviated Injury Score (AIS), sex, and RTS as predictors and was the choice of candidate models that

minimized Akaike's information criterion (AIC) and Bayesian information criterion (BIC) while demonstrating acceptable discrimination and calibration. Evidence of effect modification between RTS and ISS was sought and confirmed using likelihood ratio tests, and so an interaction term between RTS and ISS was included in the final model, the details of which can be seen in Table 2. The discrimination of the final model was excellent (area under ROC curve 0.934, 95% CI 0.931-0.938), and although the Hosmer-Lemeshow statistic was significant (p=0.011) across deciles of risk for the model, visual inspection of the plot of observed to expected mortality confirmed acceptable calibration (Figure 3). The AIC and BIC of the final model were 17,088 and 17,172, respectively. Performance of the model was found to be robust across test and in training subsets, with a nominal but statistically significant difference in AUCs of the model when applied to the entire cohort vs. in 10-fold cross-validation (0.9345 (95%CI 0.9306-0.9384) vs. 0.9346 (95%CI 0.9307-0.9385), p = 0.001). Visual inspection of Hosmer-Lemshow plots revealed no apparent differences in calibration. The FTR-T rate was then calculated over a range of threshold values for excluding deaths that occurred without adverse events. With the threshold predicted probability of mortality for reclassification of deaths based set at zero, no deaths are reclassified and all deaths occurring without a preceding adverse event are excluded, which equates in construction to FTR-E. With a threshold predicted probability of mortality for reclassification of deaths based set at 100, all deaths occurring without a preceding adverse event are re-classified and thus all included, which equates in construction to FTR-R. The effect of varying the threshold predicted probability of mortality for reclassification can be seen in Figure 4. As the threshold for reclassification increases, the number of deaths included in FTR analysis and thus the FTR rate steadily increases. At a predicted mortality threshold of 50% (indicating that non-precedented deaths with a predicted probability of mortality of >50% were excluded and the remainder classified as FTR events), adverse events were assumed to occur in 10,888/89,780 (12.1%), of whom 2,334 died for an overall FTR-R rate of 21.4%. After reclassification of non-precedented deaths below the mortality threshold of 50% as FTR cases, the final precedence rate was 60.0%.

We then compared the split-sample reliability of FTR-R, FTR-E and each of the iterations of FTR-T under which the predicted mortality exclusion threshold was varied from 0% to 100%. FTR-E demonstrated the worst split-sample reliability (rho=0.27, p=0.17) whereas FTR-R demonstrated the best split-sample reliability (rho=0.69, p<0.001). Across the calculated threshold mortalities used to define iterations of FTR-T, increasing the threshold for exclusion resulted in an increasing correlation between split samples ranging from 0.45 (p= 0.02) at an a exclusion threshold of 10% predicted mortality to 0.68 at 90% predicted mortality (Table 3).

Center-level FTR-E rates ranged from 4.2% to 22.6%, while center-level FTR-R rates ranged from 32.6% to 52.0%. The observed range of variation between these approaches was such that the center specific FTR-R rate was on average nearly 3 times greater than the center specific FTR-E rate (mean 2.91, SD 0.86). All iterations of FTR-T for a given center were by definition between that center's FTR-E and FTR-R rates (Figure 5).

Discussion

In this retrospective cohort study, we report the first large-scale investigation into FTR methodology in a trauma population. We found that the FTR-T metric demonstrated split sample reliability superior to the current FTR methodology employed in trauma research to date (FTR-E). We also found that lowest estimates of FTR rates will be derived by excluding non-precedented deaths (FTR-E) while the highest estimates of FTR rates will be derived from reclassifying non-precedented deaths as FTR cases (FTR-R). In our novel approach in which a mortality threshold is used as criteria for reclassification of non-precedented deaths, FTR estimates are bounded by the FTR-E rate inferiorly and FTR-R rate superiorly.

There is little available background literature on FTR methodology in cohorts of injured patients. In a reliability analysis in elective surgical populations, Silber et al found that the original FTR metric had greater reliability than those which excluded some fraction of the non-precedented deaths (17). In our population too, the FTR metric with the greatest split-sample reliability was the original FTR metric (FTR-R), with a rho of nearly twice that of FTR-E. Despite the reliability of this method, there are theoretical concerns which should preclude adoption of this approach in trauma. In a previous single-institution study, we reported that the fraction of non-precedented deaths was largely comprised of patients who succumbed to their injuries without antecedent adverse events (14). Under the FTR-R method, these deaths would be included as FTR events but this approach is not consistent with underlying intention of the FTR metric and unfairly penalizes centers that may care for greater proportions of mortally injured patients.

The approach of simple exclusion of non-precedented deaths in the calculation of FTR rates is appealing for its simplicity and for the fact that this is the only method that has been employed in trauma literature to date, but we found the reliability of this approach was the lowest of all examined methods. Beyond reliability issues, there are conceptual reasons why this approach cannot be endorsed. Of note, in trauma populations the fraction of non-precedented deaths far exceeds the proportion of deaths preceded by adverse events and so the way in which this non-precedented fraction is treated in FTR analysis has critical implications for the apparent FTR rate. To this point, the apparent FTR rate arrived at using simple exclusion was on average nearly 3 times lower than estimates arrived at using reclassification. Since the denominator for the FTR rate under this approach is the reported adverse event rate, the FTR-E rate is a function of the completeness of capture of adverse events and thus may underestimate the true FTR rate. Also, given that missingness in fields that capture adverse events in national data sources is a known issue (16), benchmarking efforts using this approach with these data would be highly suspect.

To overcome the shortcomings of existing approaches to calculating FTR rates in trauma, we propose here a novel solution in which expected deaths as defined by risk-adjusted mortality models are excluded and other non-precedented deaths are reclassified as FTR events. This approach demonstrates superior reliability to FTR-E while at the same time having superior face validity to FTR-R. Despite this, there are issues yet to be resolved with this methodology. Based on incremental increases in split-sample reliability, the mortality threshold that optimizes reliability as measured by Spearman's rho yet still retains face

validity with respect to reclassification of unexpected deaths appears to be 0.5. However, we recognize there is no empiric optimum threshold for determining what is and is not an "expected death", and arguments could be made for more or less stringent thresholds. While FTR-T rates will vary contingent upon the chosen threshold, this threshold would be uniformly applied to all centers in benchmarking efforts and would thus represent a fair bar. Ideally, the FTR metric used in trauma will be reproducible and well-defined but also capture those deaths which are potentially preventable. We have previously demonstrated a relationship between the FTR-E metric and preventable mortality in trauma such that using this definition FTR captures the vast majority of deaths ruled preventable or potentially preventable by mortality review panel. However, the majority of deaths that meet the technical definition of FTR were still deemed non-preventable (18). It remains to be seen whether or not the FTR-T metric we propose here will improve the sensitivity and specificity of FTR-E for capturing potentially preventable deaths.

Enthusiasm for the concept of FTR from the elective surgical literature appears to have spread to the trauma and acute care surgery community. Indeed, a recent opinion piece in the Journal of Trauma and Acute Care Surgery suggested that Acute Care Surgery should be redefined to include the essential component of 'surgical rescue' (19). Though there may be little disagreement among trauma and acute care providers that the rescuing patients from adverse events after injury is a critical part of our mission, there has been little critical thinking about how these efforts should be measured. Without a valid and reliable measurement of FTR after injury, we cannot hope to leverage variability between centers to understand the structures and processes of care that may confer survival advantages to our patients (7). An FTR metric defined specifically for trauma must balance reliability and validity, and recognize the unique characteristics of the trauma population and trauma care.

Limitations

Incomplete ascertainment is a known issue when using adverse events or rates contingent upon them as outcomes measurements. Although the missingness of the data fields for adverse events was very low (<0.1%), we acknowledge that this is a reflection of only what is recorded by clinicians and abstracted by registrars. If there was no concern for incomplete ascertainment/reporting of adverse events, FTR-E might be a reasonable metric despite the extremely low precedence rate. Pragmatically, however, it is impossible to verify complete ascertainment of adverse events in large databases. We believe that use of high-quality registries that result from rigorous mandatory reporting which are specifically designed to study adverse events and mortality guard against incompletely ascertained FTR rates. For this reason, we selected PTOS registry rather than national data sources but this leaves open the possibility that our results may not be generalizable to trauma systems in other parts of the country.

Additionally, recommendation of a 50% threshold predicted probability of mortality for exclusion in FTR for the purpose of this work is somewhat arbitrary and arguments can be made for higher or lower thresholds. As in other areas in trauma outcomes, such as the consideration of TRISS predicted survival in adjudication of preventability (20), the optimum threshold is unlikely to be empirically definable and thus will need to be reached

Conclusions

The trauma population is very different from the elective surgical population in which the FTR metric was first described and these differences must be accounted for if FTR is to be employed in the trauma literature. We propose using the FTR-T metric which reclassifies non-precedented deaths with a high probability of survival as FTR events but excludes non-precedented deaths unlikely to be survivable. Future study should focus on generalizability of this methodology to national cohorts and the intersection of this metric with preventability.

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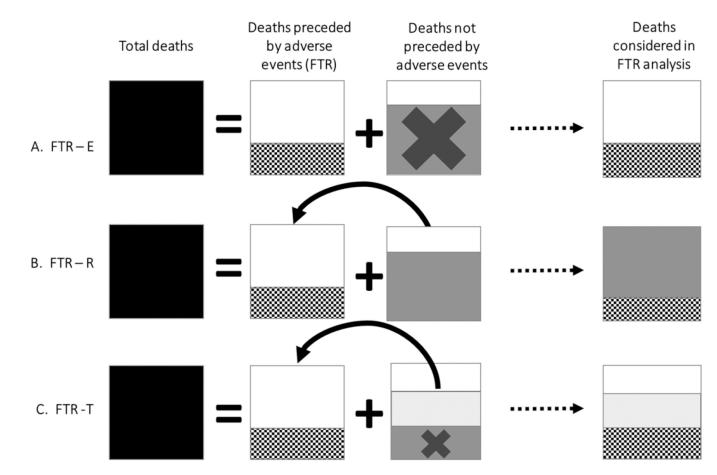


Figure 1.

A conceptual diagram of methods of calculating the Failure to Rescue rate. A.) FTR-E, exclusion; deaths not preceded by adverse events are excluded from calculation of the FTR rate. B.) FTR-R, reclassification; deaths not preceded by adverse events are assumed to represent unrecorded adverse events and are included in the FTR rate. C.) FTR-T, trauma; unsurvivable deaths not preceded by adverse events are excluded, and the remainder are reclassified as likely missed adverse event and included in the FTR rate.

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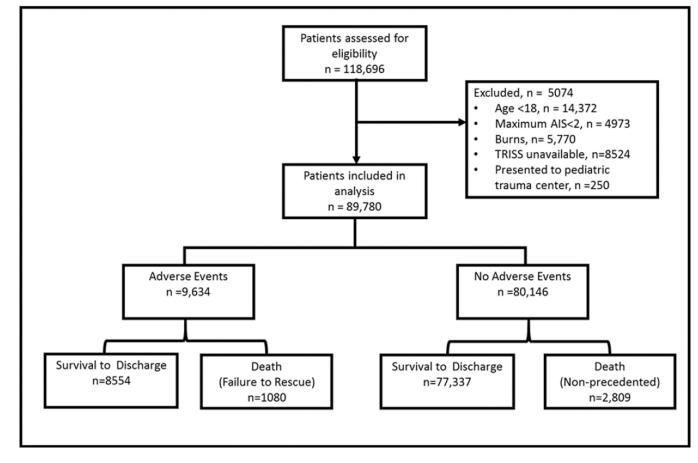


Figure 2.

Flow chart of patients who met inclusion/exclusion criteria for the study population. Abbreviations: TRISS = Trauma Revised Injury Severity Score.

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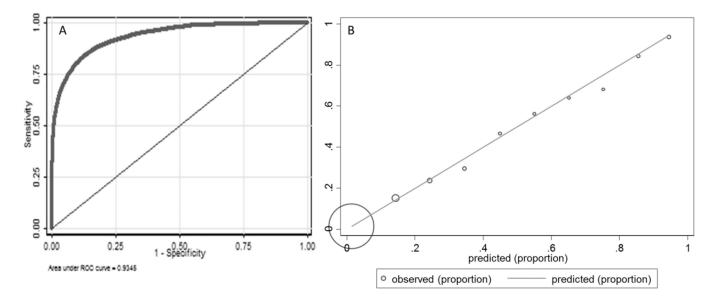


Figure 3.

Discrimination (A) and calibration (B) of the risk-adjusted mortality prediction model used to generate patient level predicted probabilities of death used in FTR-T construction.

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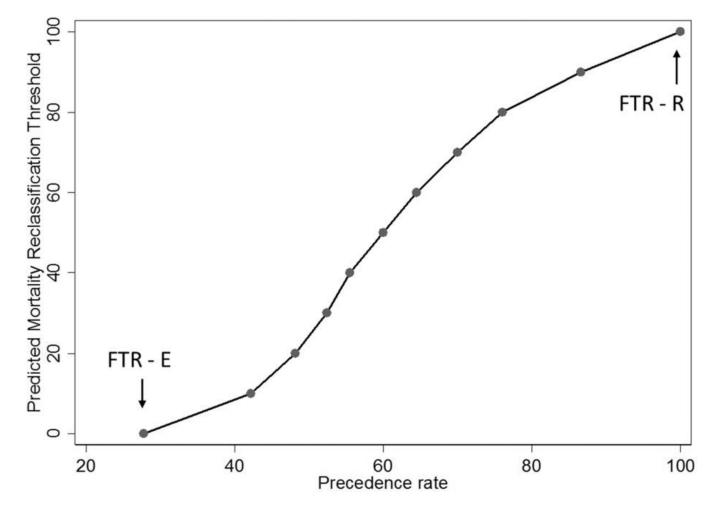
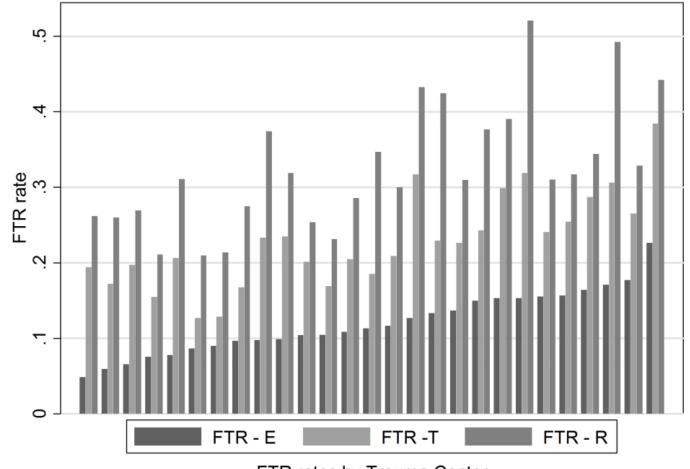


Figure 4.

The relationship between predicted mortality threshold for reclassification and precedence rate for FTR-T. A reclassification threshold set at 100 (reclassification of all deaths with less than 100% predicted probability of mortality) equates to the FTR –R rate (reclassification of all non-precedented deaths), while a reclassification threshold set at 0 (no reclassification) equates to FTR-E (exclusion of all non-precedented deaths)

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FTR rates by Trauma Center

Figure 5.

FTR-E, FTR – T, and FTR-R rates by trauma center at level I and II trauma centers in Pennsylvania. FTR-T calculated with non-precedented deaths excluded from reclassification at a threshold of 50% predicted probability of death.

Table 1

Demographics, mechanism, admission physiology as RTS, injury severity, and upon trauma center presentation for the overall cohort. Data for nonparametric continuous variables expressed as median (Interquartile Range); parametric continuous variables expressed as mean (Standard Deviation); Categorical values expressed as n (%).

	Overall Cohort n=89,780		
Age in years	57 (IQR 37-77)		
Male gender	52,983 (59%)		
Race			
Caucasian	73,615 (85%)		
African American	11,071 (13%)		
Asian	806 (1%)		
Other	1,471 (2%)		
Blunt Mechanism	83,028 (92%)		
Revised Trauma Score	7.84 (7.84–7.84)		
ISS	9 (IQR 5-14)		
Died	3889 (4.3%)		
Adverse Event	9,634 (10.7%)		

Abbreviations: ISS= Injury Severity Score.

Table 2

Final multivariable logistic regression model on mortality used to generate predicted probability of mortality thresholds for FTR-T calculations.

Variable	OR	95% CI
Age, per year	1.05	(1.05 – 1.06)
Mechanism of Injury		
Blunt	ref	
Penetrating	3.27	(2.80 – 3.81)
Underwent Operation		
No	ref	
Yes	0.59	(0.52 – 0.66)
Sex		
Male	ref	
Female	0.75	(0.69 – 0.83)
Maximum AIS	1.49	(1.39 – 1.60)
Revised Trauma Score	0.37	(0.36 – 0.38)
ISS	0.99	(0.98 – 1.00)
Interaction term, ISS #RTS	1.01	(1.01 – 1.01)

Abbreviations: OR= Odds Ratio; CI= Confidence Interval; AIS = Abbreviated Injury Scale; ISS = Injury Severity Score; RTS = Revised Trauma Score.

Table 3

The impact of varying predicted mortality thresholds for excluding non-precedented deaths in FTR-T on precedence rates and metric reliability as measured by Spearman's rho.

Predicted mortality threshold for excluding non- precedented deaths	Precedence (native) (%)	Precedence (after reclassification) (%)	rho	р
0% (FTR-E)	27.8	27.8	0.27	0.170
10%	27.8	42.2	0.45	0.019
20%	27.8	48.1	0.48	0.011
30%	27.8	52.4	0.55	0.003
40%	27.8	55.5	0.55	0.003
50%	27.8	60.0	0.59	0.001
60%	27.8	64.5	0.55	0.003
70%	27.8	70.0	0.52	0.006
80%	27.8	76.1	0.62	0.001
90%	27.8	86.6	0.68	0.000
None (FTR-R)	27.8	100.0	0.69	0.000