Special Contributions

Paramedic Rapid Sequence Intubation for Severe Traumatic Brain Injury: Perspectives from an Expert Panel

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Abstract

Although early intubation has become standard practice in the prehospital management of severe traumatic brain injury (TBI), many patients cannot be intubated without neuromuscular blockade. Several emergency medical services (EMS) systems have implemented paramedic rapid sequence intubation (RSI) protocols, with published reports documenting apparently conflicting outcomes effects. In response, the Brain Trauma Foundation assembled a panel of experts to interpret the existing literature regarding paramedic RSI for severe TBI and offer guidance for EMS systems considering adding this skill to the paramedic scope of practice. The interpretation of this panel can be summarized as follows: (1) the existing literature regarding paramedic RSI is inconclusive, and apparent differences in outcome can be explained by use of different methodologies and variability in comparison groups; (2) the use of Glasgow Coma Scale score alone to identify TBI patients requiring RSI is limited, with additional research needed to refine our screening criteria; (3) suboptimal RSI technique as well as subsequent hyperventilation may account for some of the mortality increase reported with the procedure; (4) initial and ongoing training as well as experience with RSI appear to affect performance; and (5) the success of a paramedic RSI program is dependent on particular EMS and trauma system characteristics. **key words:** paramedic; rapid sequence intubation; traumatic brain injury; intubation; prehospital; airway management; neuromuscular blockade.

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Introduction

Emergency airway management is a critical skill in the care of the injured patient in general and the patient with severe traumatic brain injury (TBI) in particular. The 2000 Brain Trauma Foundation Guidelines for the prehospital management of patients with TBI recommended endotracheal intubation (ETI) for airway protection as well as the prevention and rapid correction of hypoxemia:

> The airway should be secured in patients who have severe head injury (Glasgow Coma Scale [GCS] < 9), the inability to maintain an adequate airway, or hypoxemia not corrected by supplemental oxygen. Endotracheal intubation, if available, is the most effective procedure to maintain the airway.[1]

Although attempting ETI is considered standard of care in the prehospital management of severe TBI, many patients cannot be intubated without neuromuscular blocking agents because of the presence of clenched jaw or other airway protective reflexes. This has generated interest among emergency medical services (EMS) agencies to develop rapid sequence intubation (RSI) protocols to increase intubation success rates. Several investigators have published their experience with paramedic RSI, reporting variable success rates and

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apparently inconsistent results with regard to the impact on outcome.[2–5]

In response, the Brain Trauma Foundation assembled a panel of experts in prehospital airway management and TBI to interpret the current literature and define conditions under which paramedic RSI may be appropriate. This panel included researchers from emergency medicine and trauma surgery who have published data on prehospital RSI. The scope of this consensus statement is limited to adult patients with severe TBI (GCS < 9) who require neuromuscular blocking agents for intubation. Routine ETI in patients with TBI who can be intubated without medications has recently come under some scrutiny[4,6–12] but is beyond the scope of this document. In addition, the performance of prehospital RSI by flight nurses and physicians will not be specifically addressed here. This document represents the consensus opinions of this expert panel in addressing the following specific issues:

1. **Current Literature/Research:** How should one interpret the current literature regarding paramedic RSI of patients with severe TBI?
2. **Patient Selection:** Which patients with TBI, if any, benefit from prehospital RSI?
3. **Operator Skill:** What role does procedural performance and subsequent ventilation have on TBI outcomes following RSI?
4. **Operator Training:** To what extent is suboptimal performance of RSI a reflection of inadequate training?
5. **System Infrastructure:** What system-level factors are required to support paramedic RSI?

Question 1: What Are the Results of Outcomes Studies of Out-of-Hospital RSI in Severe TBI, and What Do They Mean?

Outcomes research evaluates the effect of an intervention on the health or outcome of a population.[13] Although several studies have evaluated the relationship between RSI and patient outcome, definitive conclusions cannot be drawn from the current literature. It is notable that the efficacy of prehospital ETI has yet to be established, with most studies evaluating this question documenting an association between prehospital ETI and increased mortality.[2–12,14–16] The one study suggesting a benefit from prehospital ETI did not adjust for important confounders, and subsequent analysis from the same system documented somewhat different results.[4,10] Although methodological limitations inherent in each of these studies limit our ability to draw definitive conclusions, these findings are provocative and suggest that an adverse relationship between prehospital ETI and outcome is plausible.

Only five studies specifically examined the relationship between outcome and prehospital RSI.[2,3,5,11,14] Sloane et al. used retrospective data from the San Diego County trauma registry to compare adult trauma patient undergoing prehospital RSI by air medical crews or emergent RSI by physicians on arrival to the hospital from 1988 to 1995.[5] Univariate analysis of 75 patients with isolated TBI revealed no statistically significant differences in 30-day mortality, length of ICU stay, or discharge destination. In addition to the small sample size, the study did not adjust for injury severity.

Bochicchio et al. described their experience with 192 patients with TBI transported to their Level 1 facility.[11] Forty-one percent of patients were intubated by paramedics in the field, with the remainder intubated on hospital arrival by inpatient personnel. Trained paramedics were allowed to use RSI to facilitate intubation. Patients were excluded from the study if intubation required more than two attempts, field intubation failed, prolonged extrication was required, death occurred within 48 hours from TBI, or transfer occurred from another facility. Intensive care unit stay, pneumonia, and in-hospital mortality rates were all higher for patients intubated in the field. No statistically significant differences could be identified between the prehospital and in-hospital intubation cohorts with regard to clinical presentation or injury severity.

Bulger et al. performed a retrospective analysis of patients treated at Harborview Medical Center in Seattle from 1998 to 2003.[2] The authors included patients with TBI (Head AIS $\geq$ 2 3) who underwent either prehospital RSI or ETI without medications. The primary outcomes were survival to hospital discharge and "good" neurological outcome (discharge GCS 14 or 15). Multivariate analysis was used to adjust for age, ISS, GCS, and the presence of prehospital hypotension or CPR. For the 2,012 patients included in the analysis, the authors observed a reduced adjusted odds of mortality (OR 0.61, 95% CI: 0.41–0.97) and an improved adjusted odds of "good" outcome (OR 1.7, 95% CI: 1.2–2.6) with prehospital RSI compared to ETI without medications. These effects appeared to be most pronounced among patients with an initial GCS of 8 or less.

Davis et al. analyzed outcomes of patients enrolled in the San Diego Paramedic RSI Trial, a prospective, large-scale implementation of prehospital RSI by ground-based paramedic units in San Diego County.[3] The trial enrolled adult patients with TBI with GCS 8 or less who could not be intubated without medications. The authors matched 352 RSI case patients from the study period (1998–2002) to 704 historical, non-intubated controls from the preceding 5 years using the following parameters: age, sex, mechanism of injury, trauma center, ISS, and AIS values for Head/Neck, Face, Chest, Abdomen, Extremity, and Skin. Using conditional logistic regression, the authors observed an association between prehospital RSI and increased adjusted odds of death (OR 1.5, 95% CI: 1.1–2.0) and a decrease in "good" neurological outcomes (OR 0.7, 95% CI: 0.4–0.9), inferred from discharge destination.

Domeier et al. performed a before-and-after analysis of the impact of a paramedic RSI program on trauma patients with a GCS 3–8 outcomes in their EMS system.[15] This included 134 patients in the "before" group and 386 patients in the "after" group, including 112 undergoing paramedic RSI. Although survival to discharge improved following implementation of the RSI protocol, outcomes were also improved in the non-intubated subgroup. Thus, the observed results may have been due to secular trends in injury patterns or outcomes.

These studies highlight important methodological issues that are critical to future research efforts in this arena. None of these studies used prospective interventional designs. Each examined different exposure groups, evaluated different questions and used different approaches to risk adjustment and statistical analysis. Furthermore, these studies were unable to adjust for other potentially important confounders, such as the integrity of protective airway reflexes. Finally, these studies used hospital discharge as the survival end point and surrogate markers to infer neurological outcome. These variations underscore the need to better identify and understand the multiple airway- and non-airway-related factors that potentially impact TBI outcomes.

Consensus opinion: There are no prospective, controlled trials available to provide definitive conclusions regarding the efficacy of paramedic RSI in severe TBI. Therefore, no definitive recommendation can be made at this time. Furthermore, the available literature addressing prehospital RSI after severe TBI is inconclusive.[2,3,5,11,14] Each of these studies evaluated a different scientific question, used a different analytic strategy, and compared different exposure groups. This underscores the need for studies that appropriately account for the impact of both airway- and non-airway-related factors on outcome from TBI.

Question 2: Which Patients, If Any, Benefit from Prehospital RSI?

Prior scientific data have not identified the group of patients who may benefit from prehospital ETI. Although physicians often intubate patients with Glasgow Coma Scores under 8 ("GCS 8, intubate"), recent efforts suggest that GCS is not an accurate surrogate marker of head injury severity.[16–18] The San Diego Paramedic RSI Trial enrolled major trauma victims with a prehospital GCS of 3–8 and "suspicion of head injury." However, 31% of patients had a head AIS of 2 or less, and 15% had a value of 0 or 1.[19] In addition, GCS provides no information regarding oxygenation status. Furthermore, previous studies have documented poor interobserver reliability for GCS scoring and potential inaccuracy with assessments performed immediately following the injury.[20–24]

One of the objectives of intubation in patients with TBI is to reverse or prevent hypoxemia. However, the detrimental effects of an aspiration event or hypoxic insult sustained prior to EMS arrival may not be reversible.[25–30] Furthermore, assessments of oxygenation and airway protective reflexes have not traditionally been incorporated into the decision to perform prehospital RSI.[16] Newer assessment tools may offer improved ability to identify patients who might benefit from prehospital RSI. Pulse oximetry (SpO2) is available in most field monitors and should be considered when assessing patients for possible intubation.[31,32] Non-invasive capnometry is already used for monitoring depth of sedation during conscious sedation and may have utility in the assessment of respiratory status in patients with TBI.[33–35] Emerging technologies, such as brain acoustic monitoring and bispectral analysis, may offer improved accuracy and consistency in the identification of individuals with severe neurological injury and are already being studied for use in the field.[36–39]

Although it is clear that GCS score is insufficient to quantify aspiration risk, subjective assessment measures, such as clenched jaw or gag/cough reflex, are not well studied and may suffer from high interobserver variability.[40–42] Newer approaches to quantify airway protective reflexes may warrant additional investigation to identify patients at high risk for aspiration.[43] The anticipated time to definitive airway management in the ED should also be considered when assessing the risk-benefit ratio for prehospital RSI because patients with longer transport times may ultimately require more aggressive prehospital airway management.

Additional research is required to refine decision tools that identify patients who may benefit from early intubation. Advanced analytical tools such as recursive partitioning and neural network analysis may offer advantages in defining these patients.[44,45] For example, application of these techniques to data from the San Diego Trauma registry suggest that patients with the combination of severe TBI and hypotension may benefit from prehospital ETI,[4] an observation that is consistent with animal and human studies documenting an interaction between hypoxemia and hypotension in the presence of severe TBI.[46,47]

Consensus opinion: The use of GCS alone is not adequate to reliably identify patients for whom the benefits of intubation outweigh the risks. Precision assessment tools, including pulse oximetry, should be used in combination with GCS to identify appropriate candidates for intubation. In addition, other factors, such as transport time, should be incorporated into the decision regarding paramedic RSI.

Question 3: Are the Adverse Outcomes with Prehospital RSI Related to Suboptimal Performance of the Procedure?

There is considerable variability in the performance of prehospital ETI across the United States.[48–50] Reported adult intubation success rates vary from 63% to 98% across EMS systems, with the highest success reported by services using paramedic RSI protocols.[51–56] Implementation of a prehospital RSI protocol in San Diego resulted in a significant improvement in the rate of successful intubation for patients with TBI from 39% to 86%.[53] However, the increase in intubation success did not translate into a mortality benefit. Therefore, it is possible that successful intubation alone is not sufficient to improve outcomes.

In the San Diego trial, unrecognized oxygen desaturation occurred frequently.[58] These transient periods of hypoxia often resulted in bradycardia and may have exacerbated the development of secondary brain injury. Secondary analysis of the San Diego data revealed an association between deep desaturations and increased mortality.[48] In addition, inadvertent hyperventilation of intubated trauma patients appears to be extremely common, with up to 50% of patients arriving in the ED with a pCO2 < 33 mmHg.[3,39] Several investigators have documented an association between prehospital hyperventilation and increased mortality in patients with TBI.[3,58,59] Excessive ventilation and the resulting hypocapnea may be detrimental to brain-injured patients based on a reduction in cerebral blood flow leading to regional cerebral ischemia. In addition, the increase in intrathoracic pressure associated with positive pressure ventilation may impair venous return, particularly in the hypovolemic patient, further compromising cerebral perfusion. Although the precise mechanism by which prehospital hyperventilation impairs outcome following TBI remains to be fully elucidated, several analyses have clearly demonstrated this association, making it imperative to control ventilation rates in the field.[3,58]

More sophisticated monitoring systems in the prehospital setting may provide a partial solution to these issues. Pulse oximetry should be used whenever prehospital RSI is considered. The use of end-tidal CO_2 monitoring has been associated with a decrease in inadvertent severe hyperventilation in patients with TBI. However, even when this monitoring is available, frequent transient episodes of hypocapnea have been reported.[47,60] Secondary analyses from the San Diego trial documented improved outcomes in patients with RSI transported by air medical crews, possibly due to more rigorous monitoring of end-tidal CO_2 and lower rates of hyperventilation in this subgroup.[61–63]

In summary, competent technical performance of RSI, including optimal management includes appropriate care before, during, and after intubation, appears to be important to outcomes after prehospital RSI. EMS systems considering paramedic RSI should incorporate training encompassing all aspects of airway and ventilation management, ongoing skills maintenance training for providers, and use of monitoring devices to identify and avoid desaturations and hyperventilation.

Consensus opinion: "Competent" performance of RSI is not limited to successful tube placement but also involves appropriate care throughout the prehospital course. This includes avoiding desaturations during RSI as well as subsequent hyperventilation, both of which may have a substantial impact on outcomes.

Question 4: What Role Does Training, Experience, and Skills Maintenance Have in RSI-Related Outcomes?

Given the complexity of knowledge and skills required to perform RSI in the field, training and experience may impact clinical performance as well as patient outcomes. Several paramedic systems using intensive training and education have achieved levels of RSI success comparable with inpatient performance of the procedure.[10,56,64,65] However, it is not known whether the quality of training is higher when limited to smaller cadres of paramedics nor whether this results in improved patient outcomes.

Dilution of ETI experience remains a significant issue for many EMS systems. Wang et al. observed that the median annual number of ETI performed by Pennsylvania paramedics was one, with 40% of paramedics performing no ETI at al.[9] Gausche et al. documented the Los Angeles County paramedic experience with pediatric intubation, which was not in the paramedic scope of practice prior to the trial.[60] Paramedics received only 6 hours of training prior to initiation of the study. Furthermore, over 2,500 paramedics received training in pediatric intubation, with an average of only 276 patients each year meeting inclusion criteria, which may partially explain why only 57% of patients in the ETI cohort were successfully intubated. Similarly, data from the San Diego Paramedic RSI Trial document that an individual paramedic would participate in an RSI procedure an average of only once every 2 years.[19] Again, this may explain the relatively low intubation success rate (84%) and high incidence of desaturations and hyperventilation. These reports suggest that the opportunity for intubation skills maintenance in some EMS systems is limited by the large number of providers "competing" for a relatively scarce procedure. Conversely, in Seattle, where the number of paramedics is restricted, each performs an average of 12 intubations per year, half of which involve the use of RSI.[2]

The impact of initial and ongoing training may also be an important factor with regard to RSI performance.

Brief initial training and limited ongoing experience with the procedure may result in both mediocre success rates as well as a high incidence of complications.[3,11] In contrast, intensive initial training that includes RSI experience with live patients, intensive ongoing training, tracking of individual experience with RSI and non-RSI intubations, and access to either simulators and/or operating room experience for remediation has resulted in high success rates with few documented complications.[2,56,67] Perhaps the best example of success with paramedic RSI comes from Wayne and Friedland, who reported success rates with a large number of paramedic RSI procedures that rival those of the ED or operating room. Only a small number of paramedics are "certified" to perform the procedure, with extensive initial and ongoing training as well as strong medical direction and quality improvement. More recently, Fakhry et al. reviewed the flight paramedic experience with prehospital RSI in Fairfax, Virginia.[67] Only six paramedics are included in the program, with intensive initial and ongoing training that encompasses more than 40 supervised intubations each year and practice on human simulators. The service reported a 97% success rate with prehospital RSI. Complications included five (2.9%) right mainstem intubations and two (1.2%) ET tube dislodgements en route. There were no unrecognized esophageal intubations observed in the 5-year study period, and arterial desaturations occurred only in the presence of cardiopulmonary resuscitation. In addition, arrival pCO_2 values were near normal at 37 mmHg. Attempted RSI added a mean of only 6 minutes to the scene time.

Consensus opinion: System differences in initial RSI training and skills maintenance may account for some of the variability in success with the procedure. Relatively small groups of highly trained paramedics who perform RSI with sufficient frequency to maintain a skill level comparable with in-hospital providers can perform prehospital RSI with high success rates, few complications, and without significant transport delays.

Question 5: What System-Level Factors Are Required to Support Prehospital RSI?

Although there has been no formal scientific evaluation to define system requirements for a successful paramedic RSI program, this panel has identified several characteristics believed to be important in this regard. These systems, which have demonstrated apparent success with paramedic RSI, can serve as models for other EMS systems that seek to implement or improve such a program. First, a careful assessment of the existing trauma system should be performed to quantify the actual or anticipated need for the procedure. Intubation success rates and estimated annual number of intubation attempts per system provider should be determined for both RSI and non-RSI intubations. This should help to estimate how the proposed program will affect intubation success rates and how patient outcomes might be improved over existing practice.

A strategy should be identified to establish or strengthen core components of the program. These components have been described in various position statements and resource documents and include system support for the RSI program and a quality assurance program that includes patient outcomes, educational infrastructure, logistical capabilities, and available hospital resources. The indications and protocols for RSI must be developed in conjunction with both EMS and hospital personnel. Systems for initial and continuing education within the system should be established. Participating providers require intensive initial training and frequent continuing education that includes didactic content as well as live- and simulator-based experience.

A system quality assurance/performance improvement program is critical to the success of a paramedic RSI program. Links between the system participants (EMS, ED, trauma, and pharmacy) ensure communication of outcomes as well as complications and other educational needs. Quality indicators should be defined up front and data collection procedures incorporated into the infrastructure of the program. These include intubation success rates, complications, ventilation parameters, patient survival, and neurological status at discharge.

All system stakeholders should be engaged early in the development of a paramedic RSI program to achieve and maintain support for the program. Logistical considerations include procedures to replace used or expired drugs, and hospital or pharmacy policies and procedures may need to be modified for the RSI program. A successful RSI program requires the collaboration of in-hospital and prehospital personnel. Operating room availability for regular supervised intubation experiences may impact the ability to implement a program and dictate the type of training available to participating paramedics. Available hospital resources can easily be overwhelmed, especially in a system with a large number of eligible paramedics.

Although many would consider an RSI program to be a desirable component of a modern progressive EMS system, each site must assess its ability to provide the infrastructure and personnel to make the program successful. Failure to provide the necessary components may doom the program to failure. The potential for worsened outcomes is real, but adverse events and patient deterioration may go unrecognized without adequate monitoring. Systems that meet these requirements should consider whether the cost and work associated with establishing or improving an RSI program will produce desired improvements in patient outcomes.

> **Consensus opinion:** A paramedic RSI program requires a supportive infrastructure that includes strong medical direction and oversight, protocol development, an implementation plan that includes both cognitive and technical training, appropriate prehospital triage, skill maintenance, and performance improvement. Paramedic RSI should not be performed in EMS systems where provider training is limited to brief introductory experiences, procedural exposure is low, and/or advanced monitoring is unavailable. The implementation of a paramedic RSI program also requires collaboration between prehospital and in-hospital personnel and should include an effective mechanism for performance improvement, including tracking hospital outcomes.

FUTURE DIRECTIONS

Additional investigation with improved methodologies to define the role of paramedic RSI must be considered a priority for EMS research. Future studies should include the use of prospective interventional designs, risk adjustment to control for variability in severity of illness, and the use of alternate mortality and neurological outcome measures.[68] For example, both shorter and longer end points, such as 7-day, 14-day, 28-day, and 1-year mortality, may prove useful. Previous studies have demonstrated that prehospital factors may have very different effects on early versus late in-hospital outcomes, and shorter end points may adequately identify mortality in certain subsets.[68] These analytical approaches may be applicable to TBI patients and other injured subsets.

In addition, many potentially confounding events occur during the subsequent ED and inpatient course that can have profound effects on outcome, making a connection between a prehospital intervention and a posthospitalization outcome difficult to demonstrate. A recent consensus document addressing this challenge defines the issues and potential solutions involved with the impact of post-EMS care on outcomes-based EMS research.[69] Variations in neurosurgical management, including the use of outdated modalities such as hyperventilation, steroids, and delayed craniotomy, are well documented and present unique analytic challenges.[6,71] Functional outcome measures may also prove more informative than surrogates of neurological outcome.[9] Specific goals for future TBI investigation include the following:

1. To conduct one or more well-designed, prospective randomized studies that control for patient factors, provider factors, situational factors, and systemic factors to evaluate the outcome of RSI in the population with severe TBI
2. To evaluate potential outcome measures in terms of their proximity to the intubation event and their ability to discriminate intubation effects
3. To use analytic techniques that allow for statistical adjustment for those variables that cannot be controlled by the design
4. To implement investigations in centers adhering to protocol-driven management of TBI to decrease the effects of confounding variables
5. To explore emerging technologies, such as brain acoustic monitoring and bispectral analysis, for their potential in field identification of appropriate candidates for intubation[36–39]
6. To use more sophisticated analytic strategies, such as recursive partitioning and neural network analysis, to help define a group of patients with TBI who benefit from early intubation.[41,42]

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