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Prehospital Ground Transport Rapid Sequence Intubation for Trauma and Traumatic Brain Injury Outcomes

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The Brain Trauma Foundation Guidelines for prehospital management of traumatic brain injury were published in 2008 and recommend "...In ground transported patients (with traumatic brain injury) in urban environments, the routine use of paralytics to assist endotracheal intubation in patients who are spontaneously breathing, and maintaining an SpO2 above 90% on supplemental oxygen, is not recommended."[1] Caution against prehospital intubation stems from associated potential adverse effects of prolonged scene times, inadvertent hyperventilation, and experience of prehospital care providers.

The guidelines are discordant with current practice in Victoria, Australia where scope of practice of intensive care trained paramedics encompasses a range of indications for intubations including neurological injury with Glasgow Coma Scale score <12. This practice has been supported by the prehospital rapid sequence intubation (RSI) randomized controlled trial (RCT) "Prehospital rapid sequence intubation improves functional outcome for patients with severe traumatic brain injury: a randomized controlled trial." *Ann Surg*. Bernard SA, Nguyen V, Cameron P, Masci K, Fitzgerald M, Cooper DJ, et al. 2010;252(6):959–65, which studied of 312 subjects with evidence of head trauma, Glasgow Coma Score ≤9, age ≥15 years and intact airway reflexes.[2]

It is the only randomized trial published of urban ground-based paramedic administration of anesthetic and paralyzing agents for neurotrauma linked to long-term (6-mo postinjury) outcomes. In the 8 years since publication in the *Annals of Surgery* it has been cited over 230 times as evidence supporting paramedic prehospital endotracheal intubation.

The RSI-RCT's headline finding—that prehospital RSI improves functional outcome for patients with severe traumatic brain injury—remains at odds with other studies that demonstrate that prehospital RSI is not associated with improved survival or improved neurological outcome.[3–6] In response to evolving and conflicting evidence, we would like to review the outcome measures of this landmark RCT.

Despite reporting high success rates of achieving endotracheal intubation, the RSI-RCT had confirmed what other studies have also demonstrated—that urban road-based paramedic intubation in adult patients with severe brain injury prolongs scene times and delays definitive in-hospital care.[7] Prolonged scene times are associated with higher mortality particularly among the subgroup of patients with hypotension, penetrating injury, and chest trauma.[8]

The primary outcome measure of the RSI study was the median extended Glasgow Outcome Scale score at 6 months. The study results demonstrated that there was no significant difference between the median GOSe score of patients intubated prehospital by paramedics compared with the patients intubated at hospital ($P = 0.28$).

One secondary outcome comparing favorable neurologic outcomes at 6 months was reported as higher in the paramedic intubated patients (51%) compared with the hospital intubation patients (39%); $P = 0.046$. This statistically significant finding appeared to refute a secondary null hypothesis and it became the major reported finding and title of the study.

The risks of interpreting results of secondary endpoints have been repeatedly highlighted. Studies are not powered to detect differences for secondary outcomes and it is more likely that positive changes in secondary endpoints are due to chance. As such, secondary endpoint results should only be used to help interpret the primary result of the trial or to generate hypotheses for future research. Additional nuances of this secondary endpoint increase the potential for a type I error. Including deceased patients may bias dichotomized survival analysis of neurologic outcomes when using the extended GOSe.[9] This issue had been recognized by Teasdale et al[9] who developed GOSe. They emphasized that "...the temptation to invent surrogate endpoints of interest to the clinician but (that) confer no clear outcome benefit to the patient must be resisted."[9] It had since been re-emphasized—before the RSI study commenced—that "...dichotomization is rarely defensible and often, will yield misleading results."[10]

While methodologically valid to compare RSI against a scale, it may have been clinically valid to exclude dead persons to determine neurologic outcome among survivors at 6 months. When removed from the analysis of survivors' functional capacities, there was no statistical significant difference in neurologic outcomes among survivors who underwent prehospital RSI compared with those who did not.

We suggest that headlining the only positive, yet potentially flawed, finding of 4 secondary outcomes when the primary outcome has been refuted demands further assessment of prehospital RSI. Neurotrauma represents a significant personal, societal, and

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MCF was a contibuting author on the original article by Bernard et al in 2010. MCF is employed as a Medical Advisor by Ambulance Victoria. The opinions expressed in this article are not the views of Ambulance Victoria.

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economic global health burden. It is clinically important to review any intervention as we attempt to reach an international consensus on the management of those with severe brain injury.

It is possible that a subgroup of patients, such as those transported by air or those with prolonged transport times, may benefit from prehospital RSI. However, it is equally possible that patients in urban areas, those in hemorrhagic shock and/or patients with surgically treatable brain injury may be harmed. Despite the extensively cited RCT, equipoise continues to exist and pending further trials, sound clinical judgment, which includes consideration of the benefits of early access to definitive care, should be applied before routine prehospital intubation after trauma.

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