Pre-hospital Rapid Sequence Intubation: The Proposed Trial



Ian Clark
Metropolitan
Ambulance Service
Victoria

For patients with severe head injury, what is the best approach to pre-hospital airway management?

- No intubation
- Intubation without drugs
- Intubation with sedation
- Rapid Sequence Intubation

This presentation:

To give an overview of the forthcoming RSI trial.

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- Literature review
- –The helicopter study of RSI
- -The proposed trial

<u>Literature review: Study 1</u>:

Patients in LA with head injury and GCS < 9 (Retrospective, not randomized)

| Not Intubated: | 714 | 43% mortality | |
|--------------------|-----|----------------|--|
| Intubated | 81 | 81% mortality | |
| (Failed intubation | 57 | 77% mortality) | |

Murray JA, Demetriades D, Berne TV, et al. Prehospital intubation in patients with severe head injury. *J Trauma* 2000; 49:1065-1070.

Conclusion: Pre-hospital intubation does not improve outcome

<u>Literature review: Study 2</u>:

Children in LA with head injury and GCS < 9 (Prospective, randomized)

No Intubation: 25 68% mortality

Intubation 36 75% mortality

Gausche M, Lewis RJ, Stratton SJ, etal. Effect of out-of-hospital pediatric endotracheal intubation on survival and neurological outcome. JAMA; 2000; 283:783-790.

Conclusion: Pre-hospital intubation does not improve outcome

<u>Literature review: Study 3</u>:

578 children in National Register with head injury and GCS < 9 (Not randomized)

No Intubation: 99 48% mortality

Intubation 479 48% mortality

Cooper A, Prehospital endotracheal intubation for severe head injury in children: a reappraisal Sem Pediatr Surg 2001; 10:3-6

Conclusion: Pre-hospital intubation does not improve outcome

<u>Literature review:Study 4</u>

- London Helicopter Emergency Medical Service
- 486 adult patients with severe head injury intubated without drugs
- 1 survived

Lockey D, et al. BMJ 2001; 323:141

Conclusion: Pre-hospital intubation (without drugs) does not improve outcome

<u>Literature review Study 5:</u>

A meta-analysis has compared no intubation vs Intubation (without drugs):

23 studies 6003 patients

Conclusion: Pre-hospital intubation does not improve outcome

Liberman M, et al. Advanced or basic life support for trauma: Meta-analysis and critical review of the literature. J Trauma 2000; 49:584

<u>Literature review: Study 6:</u>

One case-control study has suggested intubation (without drugs) improved outcome:

Intubated 565 26% mortality

Not intubated 527 36% mortality

Winchell RJ, Hoyt DB. Endotracheal intubation in the field improves survival in patients with severe head injury. *Arch Surg* 1997; 132:592-597

<u>Literature review: Study 6:</u>

And in this study RSI (by the helicopter paramedic) increased the numbers of patients able to be intubated to 86% (although mortality rate in ETT patients was higher):

Intubated 431 35% mortality

Not intubated 71 21% mortality

Winchell RJ, Hoyt DB. Endotracheal intubation in the field improves survival in patients with severe head injury. *Arch Surg* 1997; 132:592-597

<u>Literature review:</u>

Other studies of RSI:

Commonly used in the USA:

McDonald CC, Bailey B. Out-of -hospital use of neuromuscular-blocking agents in the United States. *Prehospital Emerg Care* 1998; 2:29-32

Safely used prehospital:

Wayne MA, Friedland E. Prehospital use of succinylcholine: A 20 year review. *Prehospital Emerg Care* 1999; 3:107-109, and

Sloane C, Vilke GM, Chan TC, et al. Rapid sequence intubation in the field versus hospital in trauma patients. *J Emerg Med* 2000; 19:259-264.

Severe head injury:Other airway treatment options:

Intubation with sedation only:

- •A strategy which <u>possibly</u> decreases cerebral perfusion pressure (decreased blood pressure due to high dose of drugs and increased intracranial pressure due to gagging) is regarded as <u>potentially</u> harmful
- No evidence of any benefit at this time.
- Against national and international recommendations
- Only used by paramedics in Melbourne (not be acceptable elsewhere in Australia, USA or UK).

NOT APPROPRIATE FOR TRIAL AT THIS TIME

A Preliminary Study:

Paramedics in the helicopter emergency medical service of Air-Ambulance Victoria were trained to perform RSI in late 1999.

Training:

Lecture/ manikin practice for cricothyroidotomy/
LMA/ RSI in operating theatres
Failed intubation drill
Initially supervised in the field

The Failed Intubation Drill:

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Unable to see vocal cords during initial laryngoscopy:
                    Bag/ mask/ Oropharyngeal airway
                     Retry using gum elastic bougie, "BURP"
                           Trial of "blind" placement
Immediate definitive check of position (ETCO2 / Air aspiration test)
                                         ⇒ ETT in trachea
                               ETT in oesophagus
                    Remove ETT Insert laryngeal mask airway
                                         ⇒ Now able to oxygenate and ventilate
              No, still not able to oxygenate/ ventilate with LMA
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Preliminary Study Results:

- 121 patients with severe head injury (December 99-January 2002),
- 10 intubated without drugs and 1 intubation not attempted (3/12 old baby)
- 110 attempted RSI
- 107 successful
- 3 unsuccessful, 2 managed OK with LMA, 1 attempted cricothyroidotomy
- RSI associated with excellent blood pressures, oxygen saturations and end-tidal CO₂ 's

| Airway Management | Pre RSI | Post RSI | Arrival |
|------------------------|----------|-----------|-----------|
| SBP mmHg | 120 (38) | 127 (28)# | 134 (24)# |
| Pulse (bpm) | 106 (27) | 112 (21) | 111 (20) |
| SaO₂ % | 93 (8) | 97 (6) | 99 (2) |
| ETCO ₂ mmHg | | 40 (10) | 33 (4)# |

- Summary of Literature Review and Preliminary Experience in Victoria:
- Benefit of intubation without drugs unclear, significant improvement in one study, equivocal in others, almost no survival in another.....
- RSI intuitively beneficial, but no pre-hospital RCTs
- RSI is commonly performed in USA and appears relatively "safe" with failed intubation drill.
- RSI associated with high success rate and excellent vital signs in preliminary Victorian study.

Conclusion:

A road-based pre-hospital prospective, randomized, controlled trial of RSI versus no intubation in patients with severe head injury who have intact gag/cough reflexes is justified.

The case for:

- Assures early oxygenation and ventilation, minimizes secondary brain injury from hypoxia and/or hypercapnea,
- Assures protection of the airway, protects against aspiration of vomit and subsequent pneumonitis
- Addition of LMA to "failed intubation drill" should minimize need for cricothyroidotomy

The case against:

- Very high level skill
- Risk of hypoxia during apnea and laryngoscopy,
- Risk of aspiration during paralysis and loss of cough reflex,
- Failure to intubate and ventilate during apnea may lead to hypoxia and death,
- · Unrecognised oesophageal intubation will be fatal,
- · Hypotension possible due to excessive sedation,
- Expensive for training and skills maintenance,
- · Longer scene times possible
- Low case load for most MICA paramedics

<u>RSI:</u>

There has never been a prospective controlled trial of RSI versus no intubation in an urban pre-hospital setting. However, Victoria is well placed to undertake this trial:

- Highly trained MICA paramedics,
- Excellent clinical support,
- Excellent research track record with HTS study.
- Substantial funding available from Victorian Trauma Foundation,
- •Non-consent trials still possible under Australian law (unlike USA, where such a trial would be extremely unlikely to get approval)

Study Hypothesis

That in an urban ambulance service, pre-hospital rapid sequence intubation (sedation plus suxamethonium) compared with no intubation in patients with severe head injury (GCS \leq 9) improves the extended Glasgow Outcome Score by one point at six months following injury.

Statistics

Requires 300 patients to detect one point increase in eGOCS (alpha 0.05, power 80%)

Study Methodology:

Patients: Head injury (blunt or penetrating)

GCS < 10

Gag reflex present

Will be transported by road (not helicopter)

Meets inclusion and exclusion criteria

Study Methodology 1:

Initial assessment, following usual protocols

Assess airway is patent (suction, oral airway)/ apply neck collar Assess breathing/ administer high flow oxygen Assess circulation, insert IV

Assess disability (GCS)

If patient has <u>completely</u> absent gag/ cough reflex: Intubation without drugs

If patient has any gag/ cough reflex, plus meets other inclusion criteria:

Enter study !!

Study Methodology (2):

- Eligible patient identified (Check inclusion/ exclusion criteria on laminated card in drug box),
- Opens next sequential (sealed) Airway Protocol Booklet
- •The patient is randomised to "Rapid Sequence Intubation" or "No Intubation",
- Follow directions in Airway Protocol Booklet,
- Transport to a Major/ Metropolitan Trauma Service as per State Trauma System,

Methodology (3):

Patients Randomized to Rapid Sequence Induction:

Preoxygenation 8 lit/min oxygen

Monitoring Pulse oximetry/ Capnography/ NIBP/ ECG

•IV Hartmanns At appropriate rate

Equipment All equipment for a failed intubation drill immediately available

Drugs: Fentanyl 100 microgram

Midazolam 2-10 mg (titrate to BP)

Suxamethonium 1.5 mg/kg

(Atropine 0.6 mg only for heart rate < 60/min)

Cricoid Pressure

Methodology (4):

Patients Randomized to Rapid Sequence Induction (continued):

- ·Laryngoscopy and Intubation
- Check ETT position: ODD pre ventilation/ capnography post ventilation.
- Insert orogastric tube and aspirate,
- Further sedation as required,
- Pancuronium 0.1 mg/kg for maintenance of paralysis,
- •Further midazolam 5 mg prn for sedation, or
- If unable to intubate: Failed intubation drill

Methodology (5):

- Research Assistant follows up in hospital,
- Research Assistant provides Information Sheet to family and gets consent,
- Patient gives consent if recovers.
- Assessment follow up at 3 and 6 months by <u>separate</u> Research Assistant who is blinded to treatment using extended Glasgow Outcome Coma Score.

Study Methodology (6)

- Research Assistant 1 follows up in hospital,
- Research Assistant 1 provides Information Sheet to family and gets consent,
- · Patient gives consent if recovers.
- At hospital discharge, follow up at 3 and 6 months by separate Research Assistant 2 (who is blinded to treatment) using extended Glasgow Outcome Coma Score.
- Data Safety Monitoring Committee to review every 100 patients

Current Status:

- ·Steering Committee established
- Medical Standards Committees of MAS and RAV approved
- Ethics Committees at RMH and Alfred approved
- Guardianship Board approved (consent arrangements)
- Department of Human Services approved
- Phillips Fox (legal advice for MAS insurance) approved
- Medical Subcommittee of Convention of Ambulance Authorities supported
- Victorian Trauma Foundation approved funding (>\$400K for training, equipment and two research assistants).
- Training started
- Runs for 2 years, recruits 300 patients in MAS and major cities of RAV (Geelong, Bendigo, Ballarat)

Timeframes:

- Research assistants appointed (June 2002)
- Data collection on head injury commences (June 2002)
- •Training commences (June 2002- November 2002)
- •Randomization commences (October 2002, runs until September 2004)
- •Runs for 2 years
- Recruits 300 patients
 - -200-250 in Melbourne, Geelong, Bendigo, Ballarat
 - -? 50-100 from Queensland
 - -?? South Australian Ambulance Service showing some interest in participating

Steering Committee:

METROPOLITAN AMBULANCE SERVICE, VICTORIA

DR STEPHEN BERNARD (PRINCIPLE INVESTIGATOR)

GREG COOPER

IAN PATRICK

ROYAL MELBOURNE HOSPITAL

ASSOC PROF PETER DANNE

PROF PETER CAMERON

ALFRED HOSPITAL

ASSOC PROF JAMIE COOPER

ASSOC PROF MARK FITZGERALD

RURAL AMBULANCE VICTORIA

TONY WALKER

DR JOHN EDINGTON

Associate Investigators:

ROYAL MELBOURNE HOSPITAL

Mr Batu Kavar (Neurosurgeon)

ALFRED HOSPITAL

Prof Jeffrey Rosenfeld (Neurosurgeon)

RURAL AMBULANCE VICTORIA

Dr David Eddy (Geelong) Dr John Eddington (Bendigo)

Data Safety Monitoring Committee:

Monash University Department of Epidemiology and Preventive Medicine, who will review:

Results every 100 patients

Any Adverse events

Training:

12 hours

4 hour lecture,

suxamethonium/fentanyl/pancuronium pharmacology

trial protocol

failed intubation drill

cricothyroidotomy

4 hours in OT x2

see and discuss RSI

Authorized for use in field after training completed until study commences

Benefits of the study

- <u>Establishes</u> optimal method of airway management in severe head injury
- May result in a major improvement in head injury management and outcome
- Will be relevant to Australia/ UK/ USA/NZ
- Advanced training funded
- Additional data on head injury for future studies
- Improves attitude to pre-hospital research and evidence based practice

Thankyou



