Reviewer's report

Title: Study protocol: Effectiveness of cricoid pressure in preventing gastric aspiration during rapid sequence intubation in the emergency department: a randomised controlled trial

Version: 1 Date: 26 October 2011

Reviewer: Jacques Lacroix

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Manuscript entitled “Effectiveness of cricoid pressure in preventing gastric aspiration during rapid sequence intubation in the emergency department: a randomized controlled trial” by Christopher E. Trethewy et al.

Submitted to the journal “TRIALS"
Manuscript number: 1135499368614414

SUMMARY. – In this research protocol, Trethewy et al describe a randomized clinical trial (RCT) with two arms. All adults (> 18 years) requiring an endotracheal intubation in the emergency room of the Australian participating hospitals will be considered for randomization. The only exclusion criterion is: cardiopulmonary resuscitation in progress upon arrival at the emergency department. Once consent is signed, the patient will be allocated to intubation with a standardized cricoid pressure of 30-40 Newtons, as measured by a platform scale, or to a cricoid pressure given by an assistant who will be kept unaware of the pressure s/he is given. Cricoid pressure is used in such circumstance in order to prevent gastric aspiration. The presence or absence of gastric aspiration will be done using a new test that detects the presence of pepsin in endotracheal aspirate. This test was created by one of the author. The main hypothesis of the RCT is that standardized cricoid pressure will prevent some gastric aspiration.

MAJOR COMPULSARY REVISIONS

METHODOLOGY

• Patients. – The only exclusion criterion is: cardiopulmonary resuscitation in progress upon arrival at the emergency department. Other criteria must be considered, such as aspiration pneumonia, near-drowning, etc.

• What will happen in cases where consent is not obtained?

• Intervention and co-interventions. – The cricoid pressure will be measured with a platform on which the assistant will stand up. The weight of the assistant will be subtracted to zero. Then, the assistant will be asked to push the cricoid up to a weight of –3 to –4 kg, which is reported by the authors as quite similar to 30 to 40 Newtons. No data are given showing that this is the case. Actually, the validity of this measurement is not described at all.
• The scale on the platform will be read by the assistants themselves in the experimental group, by someone else in the control group. How assistants will be blinded in the control group and who will read the scale in this group is not described.

• Compliance is not defined and how will be checked compliance is not described.

• There is a risk that by chance alone, the average cricoid pressure is similar in both groups. What will be done in such instance?

• End Points and Main Outcome Measures. – An important concern that I have is about the primary outcome: different primary outcomes are described in the abstract, in the body text of the manuscript and in the Australian registry of randomized clinical trial (RCT):
  o In the abstract of the manuscript: “Primary outcomes are: complications associated with intubation and grade of the view on direct laryngoscopy, rate of aspiration of gastric contents (determined by pepsin detection on the oropharynx/tracheal aspirates) or treatment for aspiration pneumonitis up to 28 days post-intubation”.
  o In the body text:
    • Difficulty of intubation and optimal laryngeal view.
    • Complications associated with intubation
    • Rate of aspiration (pepsin detection in samples)
    • Immediate complications associated with RSI within 30 minutes of intubation (cardiac arrest / death / severe hypotension / severe hypoxaemia)
    • Survival to 28 days / hospital discharge
  o In the Australian registry: “Aspiration rate determined by the presence of pepsin in the trachea and/or if the patient is treated for aspiration pneumonitis as an inpatient.

• The presence of gastric aspiration will be determined by the presence of pepsin in the trachea. The test that will be used to detect pepsin in new. Data on the diagnostic value of this must be reported, like sensitivity and specificity, reproducibility, precision, etc.

• The investigators recognized that gastric aspiration might happen before an intubation in severely ill patients. It is written in the discussion that they will diagnose pre-intubation gastric aspiration by doing a pepsin test on secretions collected from the oropharynx before the intubation; this must be moved into the methods section.

• Moreover, the authors must explain clearly what they will do in patients with positive pre-intubation pepsin test: will they exclude them from the analysis?

• Statistical Analysis. – The statistical analysis is not optimal. For example, it is not stated if the investigators plan to do an intent to treat analysis, they do not plan any adjustment, they do not tell us what they will do if the pepsin test is positive before the intubation, etc.
ETHICS
• Proof of ethics approval: present, but outdated.

FUNDING
• Proof of funding: reported, but no official letter from the granting agency.

MINOR ESSENTIAL REVISIONS (not for publication).
• General suggestions.
• Abbreviations and acronyms must be detailed in the body text and repeated when required in the abstract, legends of figures and tables (N, RSI, LCD, GCS, etc). The acronym SD is used with two meanings: standard deviation and Secure Digital. Some abbreviations and acronyms are not defined (BP). A list of abbreviations can be added after the discussion.

Abstract (< 350 words).
• The acronyms N must be defined.

Keywords.
• OK.

Background.
• 1st paragraph, 1st line. – “Rapid sequence intubation (RSI) is…” rather than “RSI is…”.
• 1st paragraph, last two lines: I do not understand what was compared by Mort.

Discussion.
• 1st paragraph, last sentence: “…pre-intubation aspiration will allow us…” rather than “…pre-intubation aspiration we allow us…”.

List of abbreviations.
• Please, define CP, CPR.

References.
The references must be formatted according to the editorial standards of the journal TRIALS.
• The appropriate abbreviation must be used for the name of each journal (for example, British Journal of Anaesthesia in reference 11, Am J Emerg Med in reference 15, etc).
• Reference 1. – Delete “x” at the end of the reference.
• Reference 16. – Delete “table of contents” at the end of the reference.
• Reference 28. – What is the meaning of Aorn J?

DISCRETIONARY REVISIONS.
The titles in the manuscript and in the Australian New Zealand Clinical Trials Registry are different. I prefer the latter, which is: “A randomised controlled trial of the efficacy of standard versus measured cricoid force in preventing aspiration in patients intubated in the Emergency Department.”

DECLARATION OF CONFLICT OF INTEREST
I declare that I have no competing interests.

REVIEWER
NAME: Jacques Lacroix, professor
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Level of interest: An article of importance in its field

Quality of written English: Acceptable

Statistical review: No, the manuscript does not need to be seen by a statistician.

Declaration of competing interests:
I declare that I have no competing interests.