Simulator-based evaluation of clinical guidelines

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Clinical guidelines and algorithms in acute medicine

1. High risk issues
2. Time critical procedures
3. Limited evidence of elements
4. Little or no evidence of ensemble
5. Difficult evaluation in human

→ Can human patient simulation offer solutions’
Evaluation of a new clinical guideline for rapid-sequence induction (RSI) of anaesthesia in infants – human baby vs. simulator baby

Eich C et al. Sim Health 2007
Hypotheses

1. Evaluation of clinical guidelines using a simulator-setting is feasible („the model“).
2. The new („controlled“) RSI-technique produces less unsafe actions and critical incidents and is less stressful for the provider.
3. There is a correlation between stress level and unsafe actions or critical incidents.

Eich C et al. Sim Health 2007
Methods

Study design:
- Prospective, randomised, cross-over simulator-based study
- 30 male anaesthetists of different professional status performing 2 different induction techniques
- Measuring stress and incidents

Scenario:
- Anaesthesia induction in a 4 weeks old baby boy with pyloric stenosis

Eich C et al. Sim Health 2007
Methods: Controlled variables

- **SimBaby™** with programmed scenario and 3 trends for respiratory rate, heart rate & SpO₂
  - Classic technique
  - Controlled technique
  - Recovery from hypoxia

- RSI techniques (drugs, doses & timing)

- Anaesthesia nurse (standardised assistance)

Eich C et al. Sim Health 2007
Methods: Measured variables

1. Observation
   - Unsafe actions & critical incidents

2. Ergospirometry (Cortex Metamax 3 B™ & Polar™)
   - Respiratory rate, minute volume, VO₂ & heart rate

3. Saliva analyses (Sarstedt Salivette™)
   - Cortisol & alpha-amylase

4. Stress questionnaire

Nather UM et al. Psychoneuroendocrinology 2006
Reuter M. Neuropsychobiology 2002
Quilici AP et al. Clinics 2005
Müller M. PhD Thesis Dresden University (in review)
Eich C et al. Sim Health 2007
Methods:
Measurements

1. Saliva specimen (pre-stress)

2. Saliva specimen (stress 1)

3. Saliva specimen (stress 2)

4. Saliva specimen (post-stress)
Results: Oxygen consumption

- Oxygen consumption

Mean ± 0.95 Conf. Interval

- klassisch
- kontrolliert
Results: Cortisol in saliva
Results: Subjective stress perception
Preliminary results & conclusions

1. The model of simulator-based evaluation of clinical guidelines is technically feasible.

2. There are limited correlations between the different methods of stress measurement as well as between stress and unsafe actions.

3. The new (controlled) RSI-technique seems to produce less stress and less unsafe actions and may hence be safer for the patient.
Thank you for your attention!
Clinical background: 
Apnoe tolerance in children

SaO₂ ~ 90%
1 month: 7 s

3. Methods – scenario and trends
1. Clinical background – Rapid-sequence-induction in infants

**Classic technique**

- Induction & relaxation with thiopentone & succamethonium
- Cricoid pressure
- Apnoea
- Intubation under time pressure

→ Hypoxia & complications

**Controlled technique**

- Induction & relaxation with thiopentone & e.g. rocuronium
- *No* cricoid pressure
- Shallow mask ventilation ($P_{AW} \leq 12$ mbar)
- Intubation under controlled conditions

→ *No* hypoxia, less complications?

Simulator-based evaluation of a controlled rapid-sequence-induction (RSI) technique for infants

1. Clinical background
2. Hypothesis
3. Methods
4. Preliminary results
5. Discussion
6. Conclusion
## Flow chart

<table>
<thead>
<tr>
<th>Time [min]</th>
<th>Classic RSI technique</th>
<th>Controlled RSI technique</th>
</tr>
</thead>
<tbody>
<tr>
<td>-5</td>
<td>1. Saliva specimen (pre-stress value)</td>
<td></td>
</tr>
<tr>
<td>0</td>
<td>Beginn of ergospirometry 3 min rest Briefing and beginn of scenario Preoxygenation</td>
<td>Thiopentone &amp; Suxamethonium Thiopentone &amp; Rocuronium</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Cricoid pressure No cricoid pressure</td>
</tr>
<tr>
<td></td>
<td></td>
<td>No mask ventilation Shallow mask ventilation</td>
</tr>
<tr>
<td></td>
<td>Intubation attempt after 60 s</td>
<td>Intubation attempt after 120 s</td>
</tr>
<tr>
<td></td>
<td>Further course of scenario until successful intubation and ventilation</td>
<td></td>
</tr>
<tr>
<td>10</td>
<td>2. Saliva specimen (stress value 1)</td>
<td></td>
</tr>
<tr>
<td>20</td>
<td>3 min rest End of ergospirometry 3. Saliva specimen (stress value 1) Post-stress questionnaire</td>
<td></td>
</tr>
<tr>
<td>40</td>
<td>4. Saliva specimen (post-stress value) End of trial</td>
<td></td>
</tr>
</tbody>
</table>
RSI-Evaluation – Subjektives Sicherheitsempfinden

RSI-Evaluation - Herzfrequenz

Zeit [min]

HF

Klassisch
Kontrolliert

RSI-Evaluation - Atemminutenvolumen

Zeit [min]

[Klassisch]

[Kontrolliert]

Oxygen consumption

Cortisol in saliva

RSI-Evaluation – Amylase im Speichel

4. Vorläufige Ergebnisse

1. Höhere objektive und subjektive Stresswerte bei RSI-klassisch.

2. Bedingte Korrelation zwischen den unterschiedlichen Methoden zur Stressmessung sowie zwischen Stress und unsicheren Handlungen.

3. Immer Hypoxämie bei RSI-klassisch, regelmäßig mit forcierten Maskenbeatmung ($p_{AW} > 15$ mbar).


5. Einfluss der verwendeten RSI-Technik abhängig von der klinischen Erfahrung des Anwenders.
4. Discussion

... with the audience!
6. Fazit: Lösung oder Problem?

1. Das Model funktioniert hinsichtlich Abläufen und Techniken (Lösung).

2. Die klinische Aussagekraft bzgl. Stress und unsicheren Handlungen ist limitiert (Problem).

Low-fidelity simulator made in Göttingen
The Göttingen simulator study group

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