Breathing synchronized electrical stimulation of the abdominal muscles in patients with acute tetraplegia

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Motivation and problem statement

Electrical stimulation

Study design

Experimental Setup

Preliminary results

Conclusions
Motivation and problem statement

Spinal cord injury and respiration

- Injuries at or above C3 vertebrae
  - Loss of diaphragmatic motion due to paralysis of inspiratory and expiratory muscles
  - Permanently ventilator dependent

- SCI between C4 and C8 level
  - Retain function of their diaphragm and neck muscles
  - Paralysis of expiration muscles, the abdominals, as well as intercostals
  - At least 60% reduction of inspiratory muscle strength

- SCI between T1 and T12 level
  - Paralysis of abdominal muscles
  - Impaired intercostals at upper thoracic cord lesions
Coughing

- protects lungs from inhalation of irritants
- cleans the airways of excess secretions and particulate matter

Ineffective coughing in SCI individuals

- due to diminished inspiratory capacity
- due to weakness/paralysis of the expiratory muscles
- reduced mean expiration pressure and peak expiration flow \( \sim \) around 30% of that of normal controls
  \( \sim \) preventing mucus shearing
  \( \sim \) secretion gravitate back down the airways
  \( \sim \) high incidence of respiratory and aspiration complications
  \( \sim \) predisposing the patient to bacterial colonization \( \sim \) pneumonia
  \( \sim \) great risk for atelectasis
Motivation and problem statement

**Acute phase of SCI**
- High first-year mortality
- High incidence of pneumonia / atelectasis (up to 75%)
- Increased duration of intensive care phase and increased costs
- Meticulous and vigorous pulmonary hygiene
- Routine secretion clearance

**Airways clearance therapy is required!**
- To clear proximal airways
- Chest physical therapy
- High Frequency Chest Wall Oscillation (The Vest)
- Cough-Assist device (rapidly shifting from positive to negative pressure)
- Manually assisted coughing
- Electrical stimulation assisted coughing
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## Electrical stimulation assisted coughing

### Techniques

- **Phrenic nerve stimulation** - invasive - inspiratory muscles only
- **Spinal cord stimulation** - invasive - experimental studies
- **Magnetic stimulation of the thoracic nerve roots** - expensive devices
- **Transcutaneous stimulation of expiratory muscles** (mostly abdominal muscles and rarely pectoralis major muscle)

### Transcutaneous abdominal muscle stimulation

- **Non-invasive**
- Easy to apply in order to support expiration and coughing
- Several studies showed increased maximum expiratory pressure (up to 80%), peak expiratory flow (up to 50%) when applying electrical stimulation.
- Studies showed training and carry over effects
- Similar effects on cough efficacy as manual cough assist
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**Study design**

**Prospective study**
- Current situation: 75% pulmonary complications
- Goal: <50% pulmonary complications in stimulated patients
- Follow ups: 3 and 6 month after therapy cessation
- Historical control group

**2 study phases**
- 1st phase: 15 patients (success: 9 patients without complications)
- 2nd phase: 28 patients (starts if 1st phase was successful.)
- Success of entire study: 27 out of 43 patients without complications

**Funding**
- DGVU - Deutsche Gesetzliche Unfallversicherung (statutory accident insurance)
### Inclusion criteria

- SCI lesion level C4-T3
- Injury within the last 4 weeks
- Ventilator dependent at begin of intervention
- BMI: <35
- Age: 18-70 years
- On intensive care unit
- Informed consent

### Exclusion criteria

- Acute pneumonia
- Chronic obstructive pulmonary disease (COPD)
- Progressive diseases, cardiac insufficiency
- Pregnancy
- Implants which do not allow transcutaneous ES
- No feasible electrode placement
**Intervention & stimulation protocol**

**Intervention**
- Stimulation of abdominal muscles during expiration
- Intervention duration: 90 days
- Therapy: every workday 2 stimulation session each lasting for 30 min
- Reduced standard physiotherapy to match amount of therapy in historical group

**Stimulation protocol (one therapy session)**

1. 3 min. normal breathing (rest)
2. 10 min. ES-assisted breathing with 60% of tol. stim. intensity (muscle training)
3. 5 ES-assisted coughs using 100% tolerated stimulation intensity (cough support)
4. 3 min. normal breathing (rest)
5. 10 min. ES-assisted breathing with 60% of tol. stim. intensity (muscle training)
6. 5 ES-assisted coughs using 100% tolerated stimulation intensity (cough support)
7. 3 min. normal breathing (rest)
Electrode placement

Stimulation channels – electrodes

- 4 stimulation channels
- Hydro-gel electrodes (5x9 cm)
Stimulation device

Stimulator

- RehaStim2 (HASOMED GmbH)
  - Current-controlled bi-phasic pulses
  - Maximal current amplitude: 127 mA
  - Maximal pulse width: 500 us
- Stimulation frequency: 30 Hz
- User adjusts stimulation intensity (pulse charge from 0 - 100%) ⇒ automatic mapping to pulse width and current amplitude
- Customized control program and GUI for breathing synchronized stimulation
- Serial interface to ventilation machines and spirometer
- Approval for clinical study
Synchronization of ES with breathing

**Intensive care unit**
- Evita ventilator (DRÄGER)

**Spinal injury unit**
- Elise ventilator (ResMed)
- Microlab spirometer (Carefusion)

**Different modes**
- Complete ventilation
- Assisted ventilation
- Spontaneous breathing
- Adaptation of stimulation duration during expiration
Synchronization of ES with breathing
Synchronization of ES with breathing
## Preliminary results

### System deployment
- Successfully integrated in the clinical workflow
- Operation by study nurse

### Successful completion of 1st study phase
- 9 out of 15 patients (SCI C5-C8, ASIA A,B) have been recruited and completed the study.
- Average start of therapy: 26.6 days after injury
- No pulmonary complications by now!

### Training effects
- Increasing peak expiratory flow of ES-assisted coughing over therapy sessions
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Conclusions

Breathing synchronized abdominal muscle stimulation
- ... represents a promising airways clearance therapy.
- ... might reduce pulmonary complications in acute tetraplegia.
- ... might speed-up weaning.
- ... is an automated therapy also feasible on intensive care units.

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Thank you for your attention!