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

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Unfallkrankenhaus Berlin

Outline

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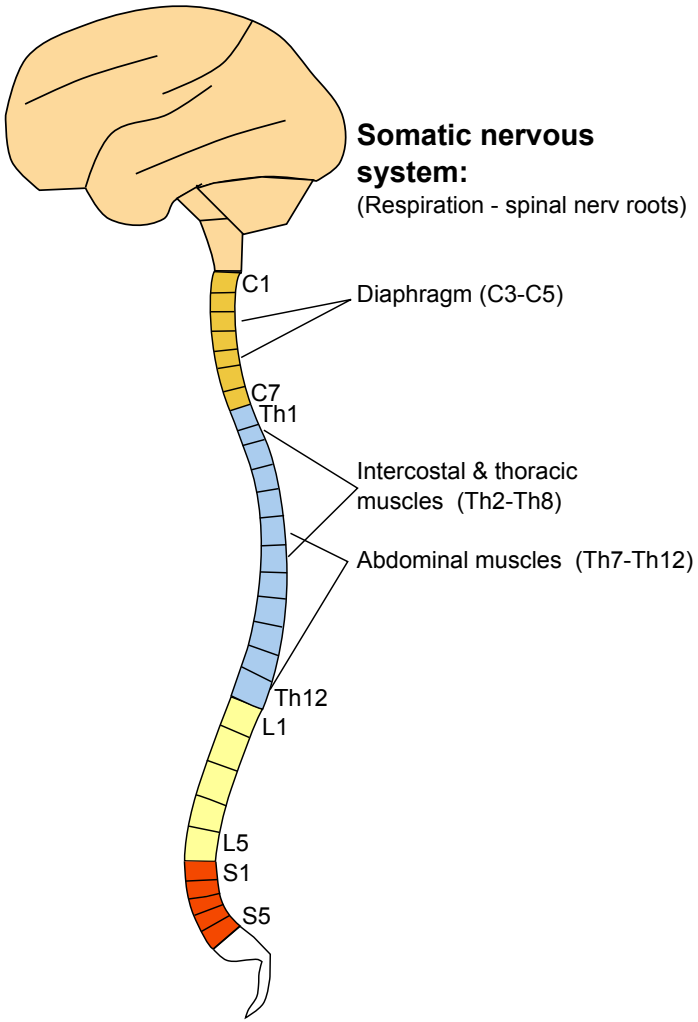
Motivation and problem statement

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



Motivation and problem statement

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 $\rightsquigarrow$ around 30% of that of normal controls

$\rightsquigarrow$ preventing mucus shearing

$\rightsquigarrow$ secretion gravitate back down the airways

$\rightsquigarrow$ high incidence of respiratory and aspiration complications

$\rightsquigarrow$ predisposing the patient to bacterial colonization $\rightsquigarrow$ pneumonia

$\rightsquigarrow$ 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

Outline

Electrical stimulation assisted coughing

Techniques

- Phrenic nerve stimulation - invasive - inspiratory muscles only
- Spinal cord stimulation - invasive - experimental studies
- Magnetic stimulation of the thoraric 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

Outline

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 and exclusion criteria

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)

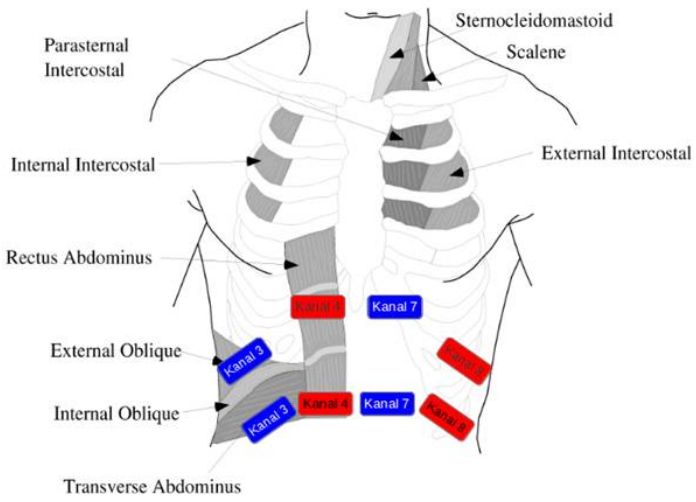
1. 3 min. normal breathing (rest)
2. 10 min. ES-assisted breathing with 60% of tol. stim. intensity (muscle training)
3. 5 ES-assisted coughs using 100% tolerated stimulation intensity (cough support)
4. 3 min. normal breathing (rest)
5. 10 min. ES-assisted breathing with 60% of tol. stim. intensity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

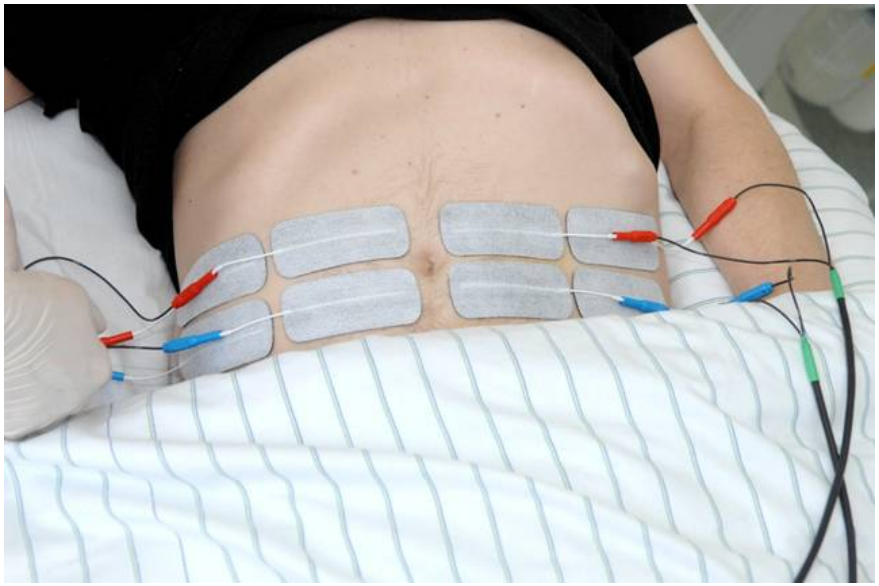
Outline

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

Outline

Preliminary results

System deployment

- Successfully integrated in the clinical work flow
- 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

Outline

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.

Acknowledgement

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Thank you for your attention!