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# ORIGINAL ARTICLE

# Mechanical ventilation or phrenic nerve stimulation for treatment of spinal cord injury-induced respiratory insufficiency

S Hirschfeld[1], G Exner[1], T Luukkaala[2,3] and GA Baer[4]

[1]*BG-Trauma Hospital, Hamburg, Germany;* [2]*Research Unit, Pirkanmaa Hospital District, University of Tampere, Tampere, Finland;* [3]*Tampere School of Public Health, University of Tampere, Tampere, Finland and* [4]*Department of Anaesthesiology, Medical School, University of Tampere, Tampere, Finland*

**Study design:** Prospective clinical study of two treatments.
**Objective:** To compare mechanical ventilation (MV) with phrenic nerve stimulation (PNS) for treatment of respiratory device-dependent (RDD) spinal cord-injured (SCI) patients.
**Setting:** Department for spinal cord-injured patients of an insurance-company-run trauma hospital in Hamburg, Germany.
**Methods:** Prospective data collection of treatment-related data over 20 years.
**Results:** In total, 64 SCI-RDD patients were treated during the study period. Of these, 32 of the patients with functioning phrenic nerves and diaphragm muscles were treated with PNS and 32 patients with destroyed phrenic nerves were mechanically ventilated. Incidence of respiratory infections (RIs per 100 days) prior to use of final respiratory device was equal in both groups, that is (median (interquartile range)) 1.43 (0.05–3.92) with PNS and 1.33 (0.89–2.21) with MV ($P=0.888$); with final device in our institution it was 0 (0–0.92) with PNS and 2.07 (1.49–4.19) with MV ($P<0.001$); at final location it was 0 (0–0.02) with PNS and 0.14 (0–0.31) with MV ($P<0.001$). Thus, compared to MV, respiratory treatment with PNS significantly reduces frequency of RI. Quality of speech is significantly better with PNS. Nine patients with PNS, but only two with MV, were employed or learned after rehabilitation ($P=0.093$). The primary investment in the respiratory device is higher with PNS, but it can be paid off in our setting within 1 year because of the reduced amount of single use equipment, easier nursing and fewer RIs compared to MV.
**Conclusions:** PNS instead of MV for treatment of SCI-RDD reduces RIs, running costs of respiratory treatment and obviously improves patients' quality of life.
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**Keywords:** spinal cord injuries; respiratory insufficiency; ventilators, mechanical; electric stimulation; respiratory tract infection

## Introduction

Permanent respiratory device dependency (RDD) due to cervical spinal cord injury (SCI) traditionally is treated with different kinds of mechanical ventilation (MV).[1,2] However, electroventilation[3] has become a choice again through its modern versions such as diaphragm pacing (DP),[4,5] carousel stimulation (CS)[6] and four-pole-sequential phrenic nerve stimulation (PNS).[7] In electroventilation, an electrical system rhythmically stimulating the phrenic nerves takes over for the malfunctioning or inaccessible respiratory centre; a normal phrenic nerve and normal diaphragm muscle are prerequisites.[8] The reason to develop the Diaphragm Pacer[4] and similar devices[6,7] was to 'free the patient from the mechanical ventilator'.[4] By using the mechanical energy of the patient's diaphragm, the patient is freed from the ventilator tube, the tracheostoma and with his helpers from the bulky energy supply of mechanical ventilators (MVs). However, when deciding on which device to use, more weight was frequently put on the higher price for the device, the surgical risk of implantation, improvement of MVs and absence of indications than was put on freedom from MV, the improved quality of speech and nursing facilitation.[1] Previous publications comparing MV and electroventilation for SCI patients did not present evidence in favour of one or the other solution, but reported the opinions of authors and patients.[9–13] We, therefore, when starting to use PNS in Hamburg, decided to collect prospectively clinically meaningful data. Our main outcomes were survival, frequency of respiratory tract infection (RI) and resocialization, that is

Correspondence: Dr GA Baer, Department of Anaesthesiology, Medical School, University of Tampere, PO Box 33014, Kasvitarhankatu 5, Tampere, Hame 33500, Finland.
E-mail: Gerhard.Baer@dnainternet.net
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living at home, learning or earning one's livelihood. The aim of the study thus was to provide data for the clinician to decide, whether to use MV or PNS in respiratory device-dependent tetraplegic patients.

## Patients and methods

We included all patients treated in the special unit for RDD, patients of the department for SCI, patients of the insurance company-run (BG) Trauma Hospital in Hamburg, Germany, from 1987 through 2006. All RDD-patients were primarily mechanically ventilated through tracheostoma. The tracheostomy tube was plugged or the tracheostoma was lost in patients on PNS. Most patients were referred from hospitals that provide primary care and rehabilitation for SCI, but have no possibility to check the function of phrenic nerves and diaphragm muscles, cannot implant a PNS and cannot condition[5] the muscle. The function of phrenic nerves and diaphragm muscles was ascertained by neurophysiologic and fluoroscopic/sonographic studies.[14] Whenever possible with patients who agreed, we implanted a phrenic nerve stimulator (Atrotech Ltd, Tampere, Finland).[7] All patients with non-functioning phrenic nerves received a mobile MV. Ventilator settings: pressure controlled through tracheostoma, positive end-expired pressure 2–8 cm $H_2O$, *P*-in 8–20 cm $H_2O$, *T*-in 1.5–2.5 s; when speaking, *T*-in is increased to 2.5 s and *P*-in to 20 cm $H_2O$. For PNS and MV, respiratory rate is 8–14 times per minute and I:E 1–1.5 or 2. No special adjustment is used for speaking with PNS. With both modes of ventilation we aimed at low respiratory frequencies, reasonable tidal volumes and normal oxygen saturation and end tidal carbon dioxide tension when using room air.

During their stay in our department, we registered the patients' time from trauma to their arrival in our department, their length of stay in our department, the pre-trauma social conditions and any possible chronic diseases or handicaps, the frequency of RIs and the quality of speech. Data on RI were also collected for the interim time outside of our department. The agreed definition of RI was the patient presented with fever, leucocytosis, increased production of secretions and the doctor in charge diagnosed the reason to be RI, with antimicrobic therapy being necessary. Three periods concerning RI appear in the course after SCI: the period before use of final respiratory device (1), of which we analysed the final 120 days only; the period using the final respiratory device inside the institution (2) and the period after institution at the final location (3). The incidence of RI in each period was calculated and is presented as RI per 100 days.

All patients were seen for a check-up once a year. Data were collected for each stay in our department separately. We registered the frequency of RI and social conditions. If necessary, data were completed from hospital files and from the special file kept in our department. SH personally collected all data for this study and also evaluated the quality of speech on a scale from 0 to 6 (0: no voice; 1: whispering, intermittently; 2: whispering; 3: low voice, intermittently; 4: low voice; 5: normal voice, intermittently; 6: normal voice). The ethical committee of our institution approved the study. All patients gave their informed consent.

*Statistics*

Due to the skew distributions, values of continuous variables are expressed as median with quartile range or range. Differences between devices were tested by the Mann–Whitney test. Differences between time periods were tested by the Wilcoxon signed-rank test. Categorical variables were tested by the Pearson's $\chi^2$-test or Fisher's exact test. Other tests are presented with the appropriate results. Statistical analyses were performed using SPSS 14.0.2 for Windows. A *P*-value less than 0.05 was considered statistically significant.

## Results

In total, 40 patients stayed in our department for full rehabilitation, 24 stayed in our special unit for 'respiratory rehabilitation' only, that is from the implantation/purchase of the respiratory device until its control was mastered by patients and caregivers; of the latter 24, 3 visited us for only evaluation of phrenic nerves and diaphragm muscles (Table 1).

Duration of rehabilitation was equal for patients on PNS (249 (7–1303) days) and patients on MV (290 (4–582) days). Recovery from implantation of the PNS and accustoming the diaphragm muscle to its continuous use (conditioning[5]) lasted only 51.06 (30–196) days and did not prolong rehabilitation. However, after beginning the continuous use of the final respiratory device with patients not primarily treated in other institutions, those on PNS ($n = 20$) remained

**Table 1** Duration of rehabilitation (days)

| | *PNS* | | | *MV* | | | |
|---|---|---|---|---|---|---|---|
| | n | *Median* | *(Range)* | n | *Median* | *(Range)* | P |
| Died in unit | 2 | 874 | (444–1303) | 4 | 273 | (68–291) | 0.133 |
| Full rehabilitation | 16 | 439 | (212–1170) | 18 | 350 | (265–582) | 0.144 |
| Respiratory rehabilitation | 14 | 71 | (7–206) | 10 | 45 | (4–166) | 0.312 |
| Stay in department | 32 | 249 | (7–1303) | 32 | 290 | (4–582) | 0.546 |

Abbreviations: MV, mechanical ventilation; PNS, phrenic nerve stimulation.
Full rehabilitation, rehabilitation to home/nursing home fitness; respiratory rehabilitation, evaluation of phrenic nerves and diaphragm muscles; introduction of final respiratory device; start of intended use of final device; stay in department, total of patients who died in our unit, received full rehabilitation or respiratory rehabilitation.

483.5 (212–1303) days, those on MV ($n=17$) 348 (257–582) days in our institution.

No patient with normal phrenic nerves and diaphragm muscles wanted MV. In total, 32 patients were treated with PNS; 32 patients remained on MV. Patients on MV were significantly older than those on PNS; there were no other significant differences between groups (Table 2). Median participation time in the study until death or 31 Dec 2006 was 3.4 years (range, 0.6–15.9) with PNS and 3.6 (0.1–10.7) years with MV. In Figure 1, a trend is obvious in favour of PNS, but the difference compared to MV is not statistically significant (log-rank $P=0.184$). Total 12 patients on PNS and 14 on MV died during the observation period ($P=0.1023$); of these, 3 with PNS and 10 with MV died of RI ($P=0.0472$).

Regarding RI (Table 3), there is no significant difference between groups in period I,. However, during both 'post-implantation' periods, 2 and 3, there are significantly fewer RIs with PNS than with MV.

There is no difference between PNS and MV for the ability to talk. The quality of speech is significantly better with PNS, where the lowest score was 3 (6 (5.25–6)), than with MV, where speech scores were frequently 1 and 2 (3.5 (2–5.75)) ($P<0.001$).

Total 2 patients on PNS and 4 on MV died in our institution; 29 on PNS and 25 on MV left home, 1 on PNS and 3 on MV to a nursing home. Today (31 Dec 2006) 20 on PNS and 18 on MV live at home. Seven patients on PNS and two on MV returned to School or High School, two patients on PNS but none on MV returned to work and all others retired (Table 4).

**Table 2** Patient demographic data on arrival at our institution

| | *PNS* (n = *32*) | *MV* (n = *32*) | P |
|---|---|---|---|
| *From accident to our hospital (n)* | 2 | 4 | |
| *Transferred (n)* | 30 | 28 | |
| *Days after trauma mean (median)* | 0.63 (3.06) | 0.12 (1.45) | |
| *s.d.* | 7.35 | 3.16 | |
| *Range* | 0.01–38.26 | 0.01–12.32 | |
| Age, median (range) | 29 (9–71) | 53 (6–77) | 0.005 |
| Male/female (*n*) | 21/11 | 25/7 | 0.266 |
| *Prior disease or handicap (n)* | | | 0.318 |
| CNS damage | 2 | 5 | |
| Metabolic/chronic disease | 7 | 9 | |
| Skeletal disorder | 3 | 5 | |
| *ASIA classification* | | | 1.000 |
| A | 29 | 28 | |
| B | 1 | 1 | |
| C | 2 | 3 | |
| *Functional neurological level* | | | 0.364 |
| C0 | 6 | 2 | |
| C2 | 22 | 25 | |
| C3 | 4 | 5 | |

Abbreviations: CNS, central nervous system; MV, mechanical ventilation; PNS, phrenic nerve stimulation.

## Discussion

We aimed at presenting prospectively registered clinically meaningful data on the fate of patients treated with PNS or MV for treatment of SCI-RDD. Survival, RI and resocialization were the main outcomes. Whereas survival and RI are well-defined entities, no validated score was available for our patients on their quality of life[15] and for their quality of speech when our study started.

*Duration of rehabilitation*

Of the first five patients using PNS, three remained exceptionally long in our department (1303, 1085, 1170 days) because their referring institutions refused to accept patients using such a strange mode of ventilation (Table 1). The problem was solved after a change of the regulations on home ventilation in 1996.

*Patients' allocation*

Patients were not randomized to PNS or MV. Instead, fate (peripheral nerve damage or not) and patient choice determined a patient's group. This drawback is present in all reports on the respiratory treatment of SCI-RDD and also in the rare studies that compared DP, CS or PNS with MV.[9–13]

In our department we permanently treat five to eight SCI-RDD patients in all stages of rehabilitation, and about 60 patients a year come for their annual check-up. Thus, every new patient meets many patients using PNS or MV. We did not try to persuade patients suitable for PNS to choose MV in order to serve as a perfect control. Neither did we try to persuade patients on MV to choose ventilation through nose/face mask, 'non-invasive ventilation',[16] because of the uncertainty of the connection, difficulties with bronchial toilet and the impairment of communication.

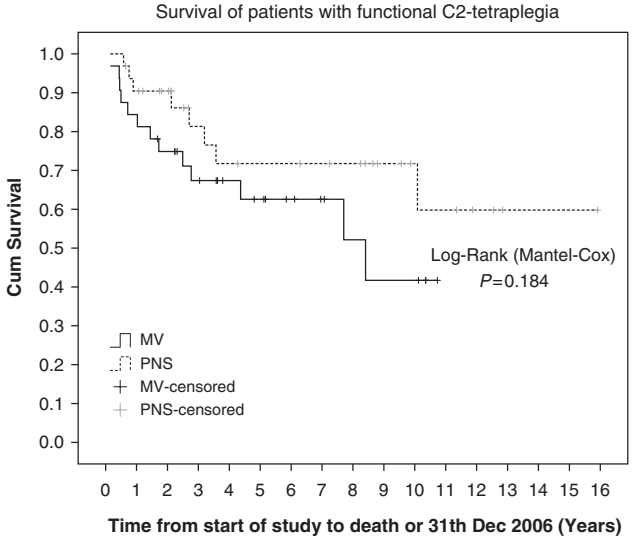


**Figure 1** Survival of patients with functional C2 tetraplegia. PNS: respiratory insufficiency treated with phrenic nerve stimulator ($n=32$). MV: respiratory insufficiency treated with mechanical ventilator ($n=32$).

**Table 3** Frequency of respiratory tract infections in 64 patients with functional C2 tetraplegia

| *Mode of ventilation* | *Period 1* | *Period 2* | *Period 3* | $P_1$ | $P_2$ |
|---|---|---|---|---|---|
| PNS | 1.43 (0.05–3.92) | 0 (0–0.92) | 0 (0–0.02) | <0.001 | 0.002 |
| MV | 1.33 (0.89–2.21) | 2.07 (1.49–4.19) | 0.14 (0–0.31) | <0.001 | <0.001 |
| $P_3$ | 0.888 | <0.001 | <0.001 | | |

Abbreviations: MV, mechanical ventilation; PNS, phrenic nerve stimulation.
Period 1, 120 days in institution before using final respiratory device; period 2, from begin of use of final device until leave from institution for final location; period 3, after arrival at final location (covers total time of follow-up, at least 1 year); respiratory insufficiency treated with PNS ($n=32$); respiratory insufficiency treated with MV ($n=32$); $P_1$, differences between periods 1 and 2 Wilcoxon signed-rank test; $P_2$, differences between periods 2 and 3 Wilcoxon signed-rank test; $P_3$, differences between devices Mann–Whitney test; numbers are median (interquartile range) of RI per 100days, calculated from counts of RI in each period.

**Table 4** State of life of 64 patients with functional C2 tetraplegia before trauma and after rehabilitation

| *State of life* | *PNS* | | *MV* | | $P_{before}$ | $P_{after}$ |
|---|---|---|---|---|---|---|
| | *Before* | *After* | *Before* | *After* | | |
| Self-employed | 2 | 0 | 1 | 0 | | |
| Employed | 9 | 2 | 11 | 0 | | |
| Learning | 14 | 7 | 4 | 2 | | |
| *Active* | 25 | 9 | 16 | 2 | | |
| Retired | 4 | 21 | 11 | 26 | | |
| No profession | 3 | 2 | 5 | 4 | | |
| *Inactive* | 7 | 23 | 16 | 30 | 0.030 | 0.093 |
| $P_{period}$ | 0.001 | | 0.002 | | | |

Abbreviations: MV, mechanical ventilation; PNS, phrenic nerve stimulation.
Numbers are patient counts; active, aiming at or earning one's own livelihood; inactive, retired or no profession; Rrespiratory insufficiency treated with Phrenic Nerve Stimulator ($n=32$); respiratory insufficiency treated with MV ($n=32$); before, state of life before trauma; after, state of life after rehabilitation; differences between devices before trauma ($P_{before}$) and after rehabilitation ($P_{after}$) were tested by Fisher's exact test and between 'before trauma' and 'after rehabilitation' in both device groups separately ($P_{period}$) by McNemar test. See the Discussion for interpretation of results.

*Survival*

There is no significant difference in our study in the duration of life (Figure 1). Carter *et al*.[9] found longer survival on MV, but estimate that 'the longevity in this group (MV) may be artificially inflated' due to the long study period that includes different ways of patient selection and different versions of devices. Esclarin *et al*.[10] report on longer life with DP than with MV, but without significant difference. DeVivo and Ivie[17] surveyed 435 SCI-RDD patients from 1973 through 1992; the main reason for premature death was pulmonary complications. RI contributes to death in 13 of 23 of our patients ($P=0.1023$); however, this occurred in 10 of 14 of our MV patients ($P=0.0472$).

*Respiratory tract infection*

We think the striking difference in RI between patients on PNS and MV (Table 3) is due to the different use of the tracheostoma. With MV, coughing is impossible, and the tube is frequently opened for suctioning. With PNS the tracheostoma is omitted or the tube is plugged,[18,19] which makes active, though weak coughing possible and suctioning unnecessary. Esclarin *et al*.[10] and Soni[13] also reported a significant difference of RI in favour of DP/PNS. Wolf *et al*.[11] found RIs in eight patients on CS and in six patients on MV, whereas Carter *et al*.[9] did not report on this detail.

*Part-time use*

We encourage our patients to use frog breathing or to use their accessory respiratory muscles in the neck intermittently, which ability facilitates nursing and improves the chance to survive respiratory device failure. All of our patients need their respiratory device during sleep. Total 10 patients on PNS and 4 on MV use their device part-time; the latter do so because of our recommendation. With PNS, additional reasons for part-time use are an intermittently working respiratory centre, one-side implantation or being younger than 10 years of age; for the latter, 12 h per day is recommended maximum stimulation time. The relation of full-time to part-time use of PNS/DP is also about the same in the patient populations of Carter *et al*.,[9] Wolf *et al*.,[11] Soni[13] and of Similowski and Derenne[12]; the latter stressed the fact that irrational beliefs frequently prevent the patients from using PNS full-time.[12] Full-time use of DP for all patients is reported only by Esclarin *et al*.[10]

*Quality of speech*

With pressure-controlled MV, patients talk during inspiration; with PNS, they talk during expiration. There is no difference between PNS and MV for the ability to talk in our study and that of Esclarin *et al*.[10] We additionally assessed the quality of speech, for which no validated tool was available when starting our study. Thus, our findings suffer from being incomparable and from an unblinded assessor. We found the quality of speech significantly better with PNS than with MV ($P=0.0005$); the same fact is also stated by Wolf *et al*.[11]

*Quality of life*

At the begin of our study no validated score measured treatment-induced changes in the quality of life of our patients.[15] Therefore, we can give only the opinions of patients and doctors, like previous authors did.[5,9–13,19] Patients and their doctors found the quality of life better with PNS than with MV: patients on PNS showed more self-confidence and no one wanted to return to MV. Patients on MV frequently regretted not to be suitable for PNS. On the

Spinal Cord Independence Measure,[20] a SCI-RDD patient on MV receives 3 of 100 possible points; when using PNS, he receives 11 points. That is just 10% of the function of a non-SCI patient, but almost four times more than being on MV.

*Resocialization*

Table 4 may give the impression that using PNS leads more frequently to an active life after rehabilitation than when using MV. However, our PNS-treated patients were significantly younger than those treated with MV; therefore, already before trauma, there are more active persons in group PNS than in group MV. Seven of the nine active PNS users were students/pupils before trauma and went on studying; two had modern professions, where manual skills are unnecessary. The trend in favour of PNS in Table 4 thus obviously is due to age, not to the type of respiratory treatment.

*Costs of respiratory treatment*

A patient on PNS with a plugged or omitted tracheostoma does not need respiratory tubes, filters and no suction catheters; obviously less money is needed for equipment and for nursing time.

In our setting, we need 1 hour per day more of respiratory nursing with MV than with PNS, which means €10 950 per year; respiratory single use equipment with MV is about €6000 per year. Similowski and Derenne[12] reported the costs per patient for respiratory equipment in their stimulated group ($n=9$) to be 66% of that in the group on MV ($n=13$). However, Wolf *et al*.[11] saw five paid nurses per patient when using CS, but 3.5 when using MV, which may be due to their more complicated stimulator. In our study and those of Esclarin *et al*.[10] and Similowski and Derenne,[12] the higher first year investment for PNS is paid off after about 3 years because of the savings in single use equipment and nursing time.

Treatment of one respiratory infection in our institution means 12 additional days of intensive care, each day costing €1610; thus one treatment costs €19 320. The costs of RI per 100 days after the introduction of the final respiratory device were thus (Table 3) €9080 with PNS and €74 962 with MV. If we add the costs of RI to those of single use equipment and additional nursing with MV, a PNS/DP would be paid off within 1 year after start of use.

## Conclusion

Treatment of respiratory insufficiency after cervical SCI with a PNS instead of MV

(1) significantly reduces upper airway infections,
(2) reduces costs for single use airway equipment,
(3) improves the quality of speech,
(4) obviously improves patients' quality of life,
(5) probably reduces mortality and prolongs life,
(6) 1 and 2 together pay off the higher primary investment with PNS during the first year after start of use of PNS.

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