Paraplegia **32** (1994) 687–693

Tracheostomy ventilation versus diaphragmatic pacemaker ventilation in high spinal cord injury

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We have made a retrospective comparative study of patients with spinal cord injury, nine with a diaphragmatic pacemaker and 13 with mechanical ventilation. Clinical outcome, cost and subjective satisfaction with both modalities have been evaluated. The functional status was the same with both types of treatment. Proper management of an electric wheelchair and optimal phonation were attained, respectively, in 100% and 89% of pacers and in 77% and 77% of mechanically ventilated. The rate of hospital discharge and satisfaction with the treatment were significantly better for pacers. The time devoted to ventilatory assistance and cost were also more favourable in this group.

Keywords: spinal cord injury; mechanical ventilation; electrophrenic nerve stimulation; respiratory failure; quality of life.

Introduction

The survival rate for patients with high spinal cord injury has increased remarkably during the past 20 years. Several reasons may have contributed, including better resuscitation techniques, quick and appropriate assistance at the site of the accident, better conditions and availability of transportation facilities, and increasingly specialised medical resources. As a result, a great number of patients with high spinal cord injury survive the acute phase, and may be given portable ventilators.

Since 1982 a total of 2800 patients have been admitted to our hospital, of which more than 1% have a lesion level above C4 and complete apnoea. This poses an important health problem because the survival time can now be very long, and therefore we should provide the autonomy which enables the patient to live outside the hospital and improve his quality of life.

The first reports on diaphragmatic pacemakers (DP) by Glenn *et al* in 1972[1] showed an alternative treatment for patients who depended on mechanical ventilators (MV). Briefly, a DP (Fig 1) consists of an external stimulus controller which generates low frequency (up to 8 Hz) pulses that are sent to a subcutaneous receptor (REC) by means of a transmitter in contact with the skin (ET.C). The electrical pulses from the receptor are conducted to an electrode implanted in the phrenic nerve 2 cm below the aortic arch (N.EL). A subcutaneous neutral electrode closes the circuit.

Both systems of ventilation are equally functional because the patient can move in the wheelchair, and phonation may be regained in the majority of cases. Virtually every high spinal cord injured patient can be adapted to a mechanical ventilator, whereas candidates for a diaphragmatic pacemaker should meet certain criteria:

- Lesion level at or above C3
- Effective electrical conduction through the phrenic nerve[2]
- Intact diaphragm muscles[3]
- Absence of lung disease
- Preserved consciousness[4–6]

Since 1982, when we began to implant diaphragmatic pacemakers,[7,8] patients dependent on mechanical ventilators or on diaphragmatic pacemakers have been closely surveyed and followed in two units, one specialising in children and the other in adults. Our goals have been: (1) comfortable sitting in chair, (2) independent ambulation in an electrical wheelchair driven by

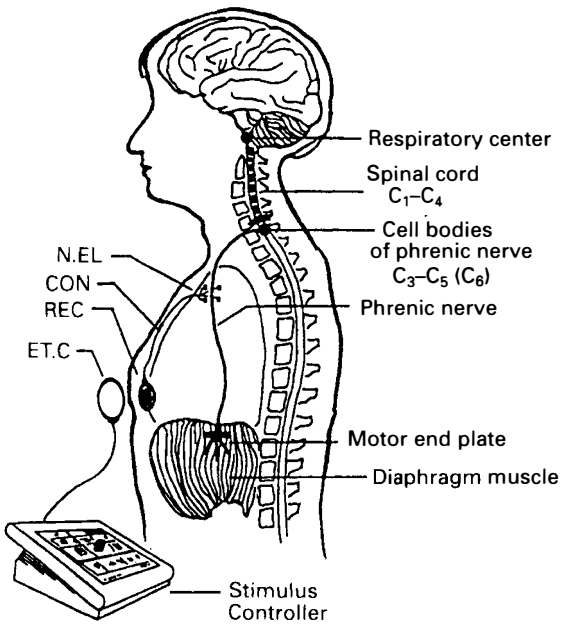

Figure 1 Components of pacemaker (Atrostech Co).

the chin, (3) phonation capability, (4) provision of the necessary technical and maintenance resources, (5) promotion of familial and social integration.[9–11]

To evaluate the overall value in these patients we have made a comparative study between both methods of ventilation, which considers clinical, economic and functional aspects, as well as the satisfaction of the patient with each modality.

Materials and method

A total of 26 patients admitted to our hospital from January 1981 to December 1991, ventilated by MV or DP, were retrospectively studied. Continuous MV was used in 17, and continuous DP ventilation in nine. Inclusion criteria for this study were high spinal cord injury with preserved brainstem function, continuous assisted ventilation, and hospitalization for a minimum of 6 months. One patient was rejected because of insufficient follow up, and three because of associated medullary disease. From the 22 remaining patients, 13 were dependent on MV (Companion 2801 (Diagniscan SA) in four, Dräger EV.800 (Dräger Hispania SA) in nine), and carried tracheostomy tube (model Shilley no. 6–8). The other nine patients had a DP (Atrostim Pekka (Atrostech) in four, Jukka Atrostech in five). Instead of a tracheostomy tube these patients have a plastic device in the tracheostomy orifice, which consists of an outer part attached to the orifice which is changed every 15 days, and a matched plug which can be opened to aspirate secretions. Both groups of patients were provided with suction straights for connection to a portable aspirator. The median follow up time for the MV group was 630 days (190–2000) and for DP group was 1100 days (185–3438). At the time of the analysis some patients had already been discharged, and others, because of social problems, were still hospitalised.

In both groups the following variables were studied: age; sex; time from the lesion to admission; ASIA scale;[12] respiratory complications; functional status; satisfaction with the treatment of the patient and the nearest family member; average time employed for ventilatory assistance of the patient; average cost of maintenance materials; survival time; and cause of death. The functional status, satisfaction with treatment and survival time were recorded from the last clinical examination, or by a telephone call made in December 1991. Information about age, level and type of lesion, admission delay, complications, time employed for ventilatory assistance, and cost were obtained from the clinical records. The respiratory complications considered were atelectasis and pneumonia, regardless of their severity. The functional state was based on the ability to remain in a sitting position at an angle of 50–90°, the skill to drive an electric wheelchair on a horizontal floor, and the use of expressive phonetic language. These variables were selected because of their relation to respiratory function. A sitting position with an angle above 45° sometimes cannot be tolerated due to malfunctioning of the pacemaker or because of excess secretions. Phonation requires a minimum expiratory volume below which it cannot be obtained.

In order to evaluate the acceptance and

satisfaction with the treatment, a questionnaire was answered by the patient and the nearest family member. It consisted of two 'yes' or 'no' items: (1) Are you satisfied with the ventilation system?; (2) Would you prefer to be connected to a portable ventilator/diaphragmatic pacemaker? To calculate the time invested in the management of both breathing systems, we considered only the actions that were clearly different—for pacemakers, change of plug, testing of transmitter and battery, and the mean number of aspirations per month; for portable ventilators, change of tubes, flex-tubes, filters and their connections, battery testing and the mean number of aspirations per month. All these maneouvres were recorded, together with their respective date, in every patient. To calculate the relative yearly cost only the differences were considered (i.e. ventilator, pacemakers, changeable devices). Assistance of the patients is carried out by the same health care personnel because both groups of patients are hospitalised in the same section. In Spain insurance companies do not pay for individual medical procedures. Instead, they pay for individual patients ($300 daily), plus extra costs (devices, drugs). The hospital pays a fixed salary to the personnel.

Statistical analysis included the comparison of mean values (Student's t test, and χ^2 or Fisher for small samples), and percentages with standard error. In the case of qualitative variables a confidence interval of 95% was used. For the complications of both treatments and because of the heterogeneity with respect to age, a descriptive analysis based on percentages was employed.

Results

The study involved 22 patients, 15 of them with MV (nine male, six female), and nine full-time pacers (seven male, two female). Table I shows the demographic features of both study groups. The main complications of treatment and the survival times are shown, respectively, in Tables II and III. Death occurred in four patients of the MV group (31%, IC 10–61%), and in one of the DP group (10%, IC 0.6–49%). Causes of death in the MV group were pneumonia in two patients, cardiogenic shock in one, and unknown in one patient. The patient with DP died at home, presumably due to inappropriate home care.

There were no significant differences with respect to functional state (Table IV). All patients in both groups were able to remain in a sitting position. Adequate management of the electric wheelchair was achieved in 77% of MV and 100% of DP. Intelligible phonation was present in 77% in MV and 88% in DP. The satisfaction with the treatment was significantly better for the DP group (Figs 2, 3).

Table I Demographic features of the sample

Features	Pacemaker (n = 9)	Ventilator (n = 13)	Significance (p value)	
Age	10.6 ± 2.5	35 ± 5.5	$p = 0.0008$	$p < 0.01$
Admission delay	225 ± 49	328 ± 87	$p = 0.32$	NS
Injury level				
C1	5	5		
C2	4	5	$p = 0.29$	NS
C3	0	3		
Frankel scale				
A	4	9		
B	3	3	$p = 0.45$	NS
C	2	1		
Aetiology				
Traumatic	8	9		
Medical	1	4	$p = 0.29$	NS

Table II Complications

	Frequency	Percentage	Confidence interval ($p < 0.05$)
Pacemaker (n = 9)			
Atelectasis	3	33 ± 16	2.9–64%
Pneumonia	3	33 ± 16	2.9–64%
Ventilator (n = 13)			
Atelectasis	6	46 ± 13	19–73%
Pneumonia	11	84 ± 10	65–100%

Table III Survival time according to treatment

Treatment	Time	Outcome
DP	185	Living
MV	190	Dead
MV	210	Living
DP	210	Living
MV	230	Living
MV	365	Dead
DP	365	Living
MV	450	Living
MV	510	Living
MV	630	Living
MV	730	Living
MV	810	Dead
MV	900	Living
DP	1095	Living
DP	1100	Dead
MV	1280	Living
DP	1245	Living
MV	1275	Living
DP	1460	Living
MV	2000	Dead
DP	3383	Living
DP	3438	Living

MV = Survival time from the moment of occurrence of the lesion.
DP = Survival time since pacemaker implantation.

Table IV Functional state

	Yes	No	Significance
Sitting			
Pacemaker	9	0	
Ventilator	13	0	NS
Voice			
Pacemaker	8	1	
Ventilator	10	3	NS
Wheelchair			
Pacemaker	9	0	
Ventilator	10	3	NS

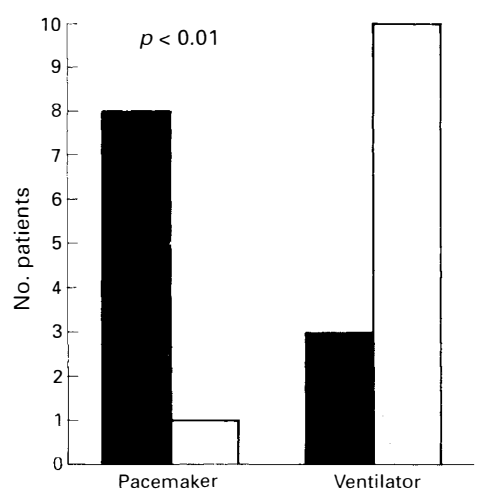

Figure 2 Acceptance of and satisfaction with treatment (patient).
■ Agree □ Disagree

The mean hospitalisation time was 370 ± 81 days for the DP group and 569 ± 96 days for the MV group. The number of discharges from the hospital was statistically higher in the DP group, from which seven patients (78%, IC 41–96%) could be released, whereas only four (31%, IC 10–61%) from the MV group could manage independently at home (Table V).

The time employed in respiratory care was 4 h 6 min shorter for the DP group (Table VI). The mean number of aspirations was 4 ± 0.8 for the DP and 11 ± 2 for the MV group. The yearly cost of material

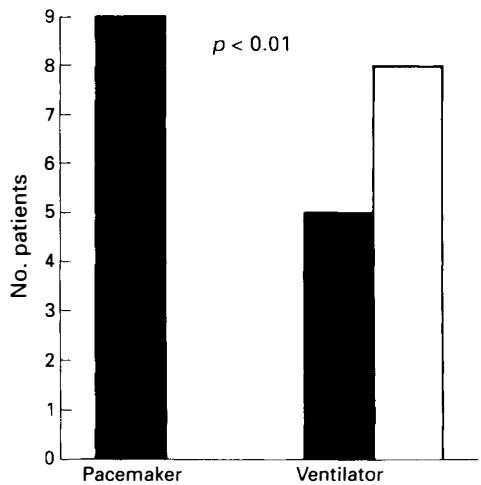

Figure 3 Acceptance of and satisfaction with treatment (family).
■ Agree □ Disagree

Table V Discharge from hospital

	Yes	No	Significance	
Pacemaker	7	2		
Ventilator	4	9	Prob: 0.04	$p < 0.05$

per patient is shown in Table VII. We have not included the cost of the basic ventilation system, which for a DP (model Jukka) is about $32500 and for a ventilator (model Dräger) approximately $16456.

Table VII Mean yearly cost of material per patient

	No./Year	Cost/$
Ventilator		
Maintenance	—	1500
Tracheostomy tubes	5	400
Filters	180	1800
Battery	1	200
Suction straight	4015	1200
Pacemaker		
Plum button	2	200
Aerial	4	800
Transmitter	1	200
Suction straight	1460	438

Discussion

The mean age of the patients studied was significantly lower for the DP group, a fact that has also been reported in the comparative study by Carter *et al.*[13] In our series, both groups were homogeneous with respect to lesion level, aetiology and admission delay. Nevertheless, it should be noted that three patients with a C3 level and phrenic nerve damage had to be excluded for DP.

Complications were frequent in both groups, as has been recognised previously by several authors.[13–17] With respect to respiratory problems, we have observed that DP patients produce less bronchial secretions, although the type of organisms

Table VI Average time spent using the ventilator and pacemaker

	Frequency (no./month)	Assistance (no. person)	Time (min)	Total (min/month)
Pacemaker				
Change plum button	2	1	2	4
Check transmitter	30	1	5	150
Test battery	30	1	2	60
Suction straight	120	1	1	120
Total				334
Ventilator				
Change tracheostomy tube	4	2	15	120
Change flex-tubes	2	2	10	40
Change filters	15	1	2	30
Filter connection	30	1	2	60
Test battery	30	1	1	30
Suction straight	300	1	1	300
Total				580

found in cultures were similar for both groups. This may be explained by the irritative effects of the tracheostomy tube on the tracheal epithelium and/or the clearly more physiological pattern of ventilation obtained with the pacemaker.[5,13]

The causes of death in the MV group coincide essentially with those reported elsewhere.[13,18,19] In contrast, only one patient in the DP group died. In this case death was due to negligent care by the family; thus it was not directly related to the method of ventilation.

The overall functional status obtained was the same with both forms of ventilatory support. However DP patients could produce phonetic modulations at a normal rhythm which resulted in better speech.

The acceptance of and satisfaction with the treatment[20] was better for both the DP patients and their respective families. This may be due to several reasons: DP occupies a smaller volume (it can be installed in the patient's belt), it has a more pleasant appearance (no need for a tube, which can be distasteful), and it is easier to manage (it requires less training for the people in charge of the patient).

After obtaining the main rehabilitation objectives, 78% of DP patients could leave hospital, whereas only 30% of MV patients were able to do so. This is due, in part, to the undoubtedly higher need for technical assistance and apprenticeship with mechanical ventilators. However, the older age of the patients and the family in the MV group may also play a role.[21,22]

From an economical point of view, MV patients required about 50 yearly additional hours for ventilatory management, and the yearly cost per patient was higher in this group. Furthermore, MV patients often needed the simultaneous assistance of two persons, whereas DP patients needed only one person and usually for a shorter time.

Acknowledgements

We are much indebted to Dr Alfonso Verdú for his valuable cooperation in the preparation of this manuscript.

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