

Author Year Country Research Design Score Sample Size	Methods	Outcome
<p data-bbox="233 1031 415 1098">Kerwin et al. 2020b</p> <p data-bbox="233 1108 415 1262">USA Case control Level 3 N = 101</p>	<p data-bbox="469 415 938 730">Population: 101 patients with acute cervical SCI and requiring MV and tracheostomy for respiratory failure, 83 males and 18 females; mean age 42 years; level of injury high (C1-C4) (n = 34) and low (C5-C7) (n = 57); complete injury (n = 85) and incomplete injury (n = 14).</p> <p data-bbox="469 741 850 808">Treatment: Patients were divided in two groups:</p> <ul data-bbox="469 819 922 1031" style="list-style-type: none"> <li data-bbox="469 819 922 919">• DPS group (n = 40): Underwent laparoscopic DPS. <li data-bbox="469 930 922 1031">• No DPS group (n = 61): Case matching patients with similar injuries. <p data-bbox="469 1041 930 1220">Outcome Measures: Ventilator liberation before discharge, days to liberation from ventilator, VT change before discharge, and mortality.</p> <p data-bbox="469 1230 922 1297">Chronicity: Patient population defined as acute.</p>	<ol data-bbox="969 415 1409 1881" style="list-style-type: none"> <li data-bbox="969 415 1409 804">1. 97% of patients in the DPS group survived, while 82% survived in the NO DPS group. This difference was statistically significant on bivariate analysis (p = 0.05) but was not significant on multivariate models that included age, sex, race, injury severity, and injury year (p = 0.69). <li data-bbox="969 814 1409 1339">2. The DPS group had a mean increase in VT of 88 ± 22 mL within 72 hours of DPS implantation, while the NO DPS group patients had a mean decrease in VT of 14 ± 32 mL at postinjury day 14. This difference was statistically different on multivariate linear regression analysis controlling for age, sex, race, injury severity, and injury year (p = 0.008). <li data-bbox="969 1350 1409 1801">3. The mean time to liberation in the DPS group was 10.1 ± 1.7 days as compared with 29.2 ± 3 days in the NO DPS group. This difference was statistically significant on multivariate linear regression analysis, including age, sex, race, injury severity, and injury year as covariates (p < 0.001). <li data-bbox="969 1812 1409 1881">4. Hospital LOS was significantly longer in the

		NO DPS group (65 ± 61 days vs. 43 ± 24 days, $p = 0.03$).
Kerwin et al. 2020a USA Case control Level 3 N = 101	<p>Population: 101 patients with acute cervical SCI and requiring MV and tracheostomy for respiratory failure, 83 males and 18 females; mean age 42 years; level of injury high (C1-C4) ($n = 34$) and low (C5-C7) ($n = 57$); complete injury ($n = 85$) and incomplete injury ($n = 14$).</p> <p>Treatment: Patients were divided in two groups:</p> <ul style="list-style-type: none"> DPS group ($n = 40$): Underwent laparoscopic DPS. No DPS group ($n = 61$): Case matching patients with similar injuries. <p>Outcome Measures: Adjusted hospital charges.</p> <p>Chronicity: Patient population defined as acute.</p>	<ol style="list-style-type: none"> Following DPS implantation, there was a statistically significant increase in spontaneous Vt compared with NO DPS ($+88$ mL vs. -13 mL; 95% CI 46 to 131 vs. -78 to 51 mL, respectively; $p = 0.004$). Median time to liberation after DPS was significantly shorter (10 vs. 29 days; 95% CI 6.5 to 13.6 vs. 23.1 to 35.3 days; $p < 0.001$). Adjusted hospital charges were significantly lower for DPS on multivariate linear regression models controlling for year of injury, sex, race, injury severity, and age ($p = 0.003$).
Kerwin et al. 2018 USA Case control Level 3 N = 101	<p>Population: <i>DPS Group, $n=40$:</i> Mean age: 45 yr; Gender: male=29, female=11; Level of injury: C1-C4= 35%, C5-C7= 65%; Severity of injury: complete=88%, incomplete=12%. <i>No DPS Group, $n=67$:</i> Mean age: 39 yr; Gender: male=54, female=7; Level of injury: C1-C4=33%, C5-C7=67%; Severity of injury: complete= 82%, incomplete= 15%.</p> <p>Intervention: Patients either underwent diaphragm pacing system implantation or did not.</p> <p>Outcome Measures: Ventilator days, VAP.</p> <p>Chronicity: Patient population defined as acute.</p>	<ol style="list-style-type: none"> There were no significant differences between groups in terms of the number of days spent on ventilators. There were no significant differences between groups in terms of the rates of VAP.
Duarte et al. 2021	<p>Population: 10 ICU patients submitted to tracheostomy due to cervical SCI (AIS A); 8 males</p>	<ol style="list-style-type: none"> Total IMV time was 1.77 times shorter in patients in

<p>Brazil Case control Level 3 N = 10</p>	<p>and 2 females; mean age 28.5 years. Intervention: TEDS combined with standard weaning protocol (SWP) or SWP alone (n = 4). TEDS training consisted of two daily 20-min sessions 7 days a week. Electrical stimulation device was triggered manually once every two breaths using verbal cues. A dual channel unit with self-adhesive electrodes (attached to the left and right midaxillary line at the level of the sixth, seventh, and eighth intercostal spaces, and to the paraxiphoid region) was used. Outcome Measures: Time of IMV via orotracheal tube, time of IMV via tracheostomy, ventilator WT, total IMV time, ICU LOS, overall hospital LOS, Sepsis-related Organ Failure Assessment (SOFA), and APACHE II scores. Chronicity: Time since injury not specified but patients were included at ICU.</p>	<p>the TEDS relative to patients in the SWP group.</p> <ol style="list-style-type: none"> 2. LOS in ICU was 2.54 times shorter in patients in the TEDS group relative to patients in the SWP group. 3. Weaning time in the TEDS and the SWP group was 28 ± 15 and 50 ± 19 days, respectively. 4. The mean number of training sessions (in the TEDS group) required for ventilator withdrawal was 47, spread across 23 days on average.
<p>Esclarin et al. 1994 Spain Case control Level 3 N = 22</p>	<p>Population: 22 participants with either: diaphragmatic pacemaker (DP) (n=9) or MV (n=13); mean (SD) age: 10.6(2.5) years (DP group) and 35(5.5) years (MV group); Injury level: C1 (n=10), C2 (n=9) or C3 (n=3). Treatment: Diaphragmatic pacemaker or MV. Retrospective study with follow up information from last clinical examination or by telephone call. Outcome Measures: Respiratory complications (atelectasis and pneumonia); functional status (ability to remain seated at 50-90°, skill to drive electric wheelchair, use of</p>	<ol style="list-style-type: none"> 1. Respiratory problems: DP group produced less bronchial secretions; type of organisms found similar for both groups. 2. No significant differences between groups with respect to functional status. 3. Satisfaction with treatment significantly better for the DP group. 4. Mean yearly cost of materials higher for MV group. 5. Deaths: 4 deaths in DP group: pneumonia (n=2), cardiogenic shock (n=1),

	<p>phonetic language); satisfaction with treatment; cost of maintenance materials; cause of death.</p> <p>Chronicity: Time from the lesion to admission was 225 ± 49 days in the pacemaker group and 328 ± 87 in the ventilator group.</p>	<p>unknown (n=1). 1 death in MV group, presumably due to inappropriate home care.</p>
<p>Nakajima & Sharkey 1990 Japan Case series Level 4 N = 15</p>	<p>Population: n = 15, C1-C3, brainstem tetraplegia.</p> <p>Intervention: Phrenic nerve (14 – neck, 1 – thorax) stimulation.</p> <p>Chronicity: Interval from injury to implantation was 3 to 35 months.</p>	<ol style="list-style-type: none"> 1. 11/15 achieved full time pacing. 2. 2/15 achieved half-time pacing. 3. 2/15 showed no response: <ol style="list-style-type: none"> a. One developed perineural fibrosis around the phrenic nerve thereby inhibiting stimulation. b. The other (a four-year-old child) showed loss of nerve viability.
<p>Sharkey et al. 1989 USA Case series Level 4 N = 15</p>	<p>Population: N = 15, high cervical tetraplegia.</p> <p>Intervention: Phrenic nerve (14/15 neck and 1/15 thoracic) stimulation.</p> <p>Chronicity: Interval from injury to implantation was 3 to 35 months; with a mean interval being 13 months.</p>	<ol style="list-style-type: none"> 1. 13/15 achieved full time pacing (including 1 who at the time of follow up did so for 16 years). 2. 2/15 achieved half-time pacing. 3. Complications: <ol style="list-style-type: none"> a. Equipment failures, in one case. b. Fibrosis around the electrode resulted in failure to stimulate the nerve, in another case. c. Infection required the removal of the system.
<p>Posluszny et al. 2013 USA Case series Level 4 N = 29</p>	<p>Population: N=29 (27M, 2F); of which N=7 were non-stimulable (7M); mean (range) age: 31.4 (17-65).</p> <p>Intervention: Diaphragm pacer implantation.</p>	<ol style="list-style-type: none"> 1. 16/22 completely weaned within a mean of 10.2 days, 18/22 within 180 days. 2. 3/22 partially weaned (mixture of MV and pacer). 3. 8/22 complete recovery of respiration and pacer removal.

	<p>Chronicity: Elapsed time from injury to surgery was 40 days (range from 3 to 112).</p>	<p>4. One patient successfully implanted but had life-prolonging measures withdrawn.</p>
<p>Elefteriades et al. 2002 USA Case series Level 4 N = 12</p>	<p>Population: N = 12, C1 - C2 tetraplegia. Intervention: Bilateral phrenic nerve stimulation and diaphragm conditioning. Chronicity: Time after injury to pacing ranged from 3 to 32 months.</p>	<p>1. Long-term follow up outcomes.</p> <ul style="list-style-type: none"> a. 6/12 paced full-time (mean 14.8 years). b. 1/12 paced full-time for 6.5 years before lapsing to part time. c. 3/12 paced for an average of 1.8 years before stopping. d. 2/12 were deceased: 1 paced for 10 years. <p>2. Patients who stopped pacing full-time did so due to inadequate financial or social support, or because they were institutionalized.</p>