Diaphragm Pacing in Spinal Cord Injury Patients: Long-term Follow Up From the Initial FDA Trial

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**Objective:** Analysis of original clinical trial participants who were implanted with diaphragm pacing (DP) system.

**Design/Method:** Prospective analysis of clinical trial patients implanted with DP system under the FDA IDE/approved protocol. All patients underwent laparoscopic diaphragm motor point mapping with electrode implantation and subsequent diaphragm conditioning and ventilator weaning.

**Results:** Between March 2000 and March 2008, 41 SCI patients were implanted, at a single center, during the initial clinical trial. All patients were dependent on tracheostomy mechanical ventilation. There were 32 males. Eighty-five percent had C1 and/or C2 involvement. Injuries were a result of MVA (17), sports (16) and other (8). The average age at time of injury was 22 years (2–70) and average age at implant was 30.9 (18–74). Time from injury to implant averaged 4.9 years (0.3–25 years). All patients with intact lower motor neurons successfully achieved 4 hours of continuous pacing, the primary end point of the trial. 63% (26) used DP 24 hours a day continuously. 32% (13) use DP at least 10 consecutive hours daily. There have been 17 deaths: 1 from homicide, 3 urosepsis, 4 cardiac, 1 mastocytosis, 1 complication from decubiti, 1 ventilator disconnect (was using part time), 1 complications of guillian barre, 1 malnutrition and withdrawal of care, 4 unknown. Two patients had electrode removal after recovery of volitional breathing. Two patients were decannulated and one downsized to stoma stent. There is total of 323 years of DPS use with three patients lost to follow up after an average of 5 years of DPS use. The average follow up of the 38 patients is 8.1 years (up to 13.3 years) with two patients having recovered function after an average of 1.2 years of DP use. Five patients required system replacement all done as outpatient procedures: infected wires (1), broken or non-functional single internal electrode (2), replacement of obsolete internal connector system (2).

**Conclusion:** This review encompasses data showing DP use up to 13 years. Twenty one clinical trial patients continue to use DP as their primary mode of ventilation. There have been no DP related deaths and no deaths from pneumonia. The DP system has proven to be durable and, in this patient population, eliminated pneumonia as the leading impact on the reduction in life expectancy.

**Long Term Mortality**

- No device related deaths
- No pneumonia
- 1 infection
- 1 ileus
- 1 abscess
- 1 myocarditis
- 1 complications of denial
- 1 ventilator disconnect (part time DP use)
- 1 complication Cerebral palsy and withdrawal of care
- 4 unknown

**Device Results**

- Five System Revisions as outpatient procedures
- 2 non-functional internal electrodes
- 1 after traumatic injury
- 1 heart arrest
- 2 replacement of obsolete internal connector system
- Of the 364 total implanted electrodes only 3.2% episodic failure after an average use of 8 years per electrode

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**Other Results**

- 2 patients with full recovery of volitional breathing – electrodes removed
- 2 patients were decannulated of mechanical ventilation
- Paresthesias: Transiently, post DP
- Routine downsizing of thoracostomies

**Background**

- Ventilator Dependent Spinal Cord Injured Patients
  - Average yearly cost: $177,200 (after serials paid)
  - Decreased mortality: 20–60%, increased life expectancy by 5–20 years
- Neurological system (CIDP, MS) have a higher morbidity with DP
- Upper G2 due to MS were vital in 19
- Lower_Fused spinal SCI cases

- VP shunts and other acute conditions
  - Viability during 10 hours of hypotension in vitro
  - 4% of ventilator days spent weaning

**Post FDA Approval Experience**

- Multi-center report describing DP early after injury
- No cardiac mortality
- 81% implanted completely weaned from ventilator
- 90% had complete recovery of neurogenic respiratory muscles and DP area were removed
- Using the electronics to monitor for recovery – SNR (impedance ratio)

**The Future: Decrease ICU Days for all Traumatic Injuries**

- Decrease ICU days by increasing ventilator settings
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**Nobody Chooses to go Back to Ventilators**

- Many patients have gone from being dependent on ventilator to DP at a national meeting (savings of $70,000)
- DP is used as a bridge to assist patients and ventilator days

**Why Temporay Diaphragm Pacing?**

- Avoid complications from ventilator
- Avoid complications from ventilator

**Changing the Paradigm in the ICU**

- Diaphragm Pacing in the ICU
- Early Implantation and Mechanical Ventilation
- Management of Respiratory Failure

**Contact Information**

- Program of Visceral Acuity
- Program of Visceral Acuity

**FDA IDE Clinical Trial Primary Site**

- March 2000 through March 2008
- 42 Patients Enrolled, 41 Implanted
- All dependent on tracheostomy mechanical ventilation
- 32 males, 9 females
- Age of Injury: 2–70 (22 years average)
- Age at implant: 18–74 (31 years average)
- Level Injury:
  - C1: 3
  - C2: 5
  - T1: 5
  - T2: 2
  - T3: 3
  - T4: 4
  - T5: 1
  - T6: 1
  - T7: 1
  - T8: 1
  - T9: 1
  - T10: 1
  - T11: 1
  - T12: 2

- Mechanical Injury: MVA (17), Sports (16), Other 8
- Injury to implant >4 months to 20 years (14 avg)

Diaphragm Pacing (DP): Conclusions

- DP is safe
- DP is durable for long term use
- DP can remove patients from the ventilator
- Early use would be recommended
- All SCI patients on the ventilator should be offered DP