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(21) International Application Number: PCT/US98/09977 (22) International Filing Date: 15 May 1998 (15.05.98) (30) Priority Data: 60/046,746 16 May 1997 (16.05.97) US (71)(72) Applicants and Inventors: FARRELL, Peter, Craig [AU/US]; 12475 Rue Fountainbleau, San Diego, CA 92131 (US), PACE, Gary, William [US/US]; 6913 Hunters Way, Raleigh, NC 27615 (US). (74) Agents: SORENSEN, Andrew, D. et al.; Holland & Hart L.L.P., Suite 3200, 555 17th Street, P.O. Box 8749, Denver, CO 80201-8749 (US).		(81) Designated States: AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CZ, DE, DK, EE, ES, FI, GB, GE, GH, GM, GW, HU, ID, IL, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, UA, UG, UZ, VN, YU, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, NE, SN, TD, TG). Published <i>With international search report.</i> <i>Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.</i>	
(54) Title: NASAL VENTILATION AS A TREATMENT FOR STROKE			
(57) Abstract A new treatment and apparatus for acute and chronic treatment is described here which incorporates nasal ventilation, with or without concomitant drug therapy, using continuous positive airway pressure (CPAP) or bi-level pressure treatment or variants thereof, including devices which automatically set their pressures based on physiologic data inputs.			

NASAL VENTILATION AS A TREATMENT FOR STROKE

FIELD OF THE INVENTION

The present invention relates to a method of treatment and apparatus for stroke patients.

BACKGROUND OF THE INVENTION

Stroke, or brain attack as it is commonly called, can be caused by either vascular hemorrhage or vascular blockage with the latter accounting for about 80% of the events which lead to a stroke. Stroke is associated with considerable morbidity in terms of long-term neurological deficit and the risk of subsequent stroke as well as mortality post stroke is considerable in stroke patients. Treatment in the acute phase typically entails the invasive administration of clot dissolving drugs within the first three hours of the stroke as well as stabilization of cardiovascular function and vital signs. Post stroke therapy can include intensive and costly rehabilitation depending on the degree of neurological deficit.

Continuous positive airway pressure (hereinafter CPAP) has been identified as a method of treatment for sleep disorders, and in particular, sleep apnea. The application of CPAP for sleep disorders was first introduced in U.S. Patent No. 4,944,310. This patent described the application of continuous positive airway pressure being applied to the patient, through the patient's nares, to treat sleep disorders, including obstructive sleep apnea. It has been found that the application of pressure which exceeds atmospheric pressure, typically 4 to 15 centimeters of H₂O is useful in treating sleep

disorders. However, prior to this invention, the application of CPAP as a method for treating stroke patients has never been known.

There exists a need for a method of treatment for stroke patients which is non-invasive, and does not include the use of drugs.

There also exists a need for the treatment of stroke patients which is inexpensive and does not require a medical facility or hospital.

Object of the Invention

It is the object of the present invention to address one or more of the above needs.

Summary of the Invention

Accordingly, in a first aspect, the present invention provides a method for the treatment of a patient who has suffered a stroke, said method comprising the application of continuous positive airway pressure to said patient at least during the acute phase of the stroke.

Preferably, the acute phase of the stroke occurs within the first three hours of the onset of the stroke.

In a second aspect, the present invention provides an apparatus for the treatment of stroke patients, said apparatus comprising:

- (a) an airflow generator;
- (b) an interface adapted to fit a patient; and
- (c) a conduit for the flow of air from said generator to said interface,

said airflow being delivered to said interface at a pressure which exceeds atmospheric pressure for at least a portion of a breathing cycle of said patient at least during the acute phase of said stroke.

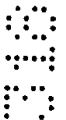
More particularly, there is provided a new treatment and apparatus for acute and chronic treatment of stroke patients is described here which incorporates nasal ventilation, with or without concomitant drug therapy, using continuous positive airway pressure (CPAP) or bi-level pressure treatment or variants thereof, including devices which automatically set their pressures based on physiologic data inputs.



Detailed Description of the Preferred Embodiment

Nasal CPAP treatment has been traditionally used for the management of patients with obstructive sleep apnea where CPAP acts as a pneumatic splint to maintain upper airway patency and therefore ensures free flow of air while the patient sleeps. The current invention describes the use of positive pressure ventilation, which may include CPAP, bi-level pressure, or variants thereof, for stroke patients. The use of CPAP treats stroke patients by improving arterial blood oxygen levels and reducing arterial carbon dioxide levels as well as improving auto-regulation of, for example, blood pressure, cardiac output and ventilation. Improvements in morbidity, such as rate and degree of recovery of vital signs and patient stabilization in the acute phase, is an expected benefit. Also, an improvement in neurological deficits in the short and/or long term is an expected benefit.

It is understood that while the invention has been described above in conjunction with the preferred method and preferred embodiment, the description and examples are intended to illustrate but not limit the scope of the invention.



The claims defining the invention are as follows:

1. A method for the treatment of a patient who has suffered a stroke, said
 5 method comprising the application of continuous positive airway pressure to said patient
 at least during the acute phase of the stroke.
2. The method of claim 1, wherein the acute phase of the stroke occurs
 within the first three hours of the onset of the stroke.
3. The method of claim 1 wherein said pressure is applied in a bi-level
 10 fashion.
4. The method of claim 1 wherein said patient's arterial blood oxygen
 level is improved.
5. The method of claim 1 wherein said patient's carbon dioxide blood
 level is reduced.
- 15 6. The method of claim 1 wherein auto regulation of blood pressure,
 cardiac output and ventilation is improved.
7. An apparatus for the treatment of stroke patients, said apparatus
 comprising:
 - (a) an airflow generator;
 - (b) an interface adapted to fit a patient; and
 - (c) a conduit for the flow of air from said generator to said interface,
 20 said airflow being delivered to said interface at a pressure which exceeds atmospheric
 pressure for at least a portion of a breathing cycle of said patient at least during the acute
 phase of said stroke.

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