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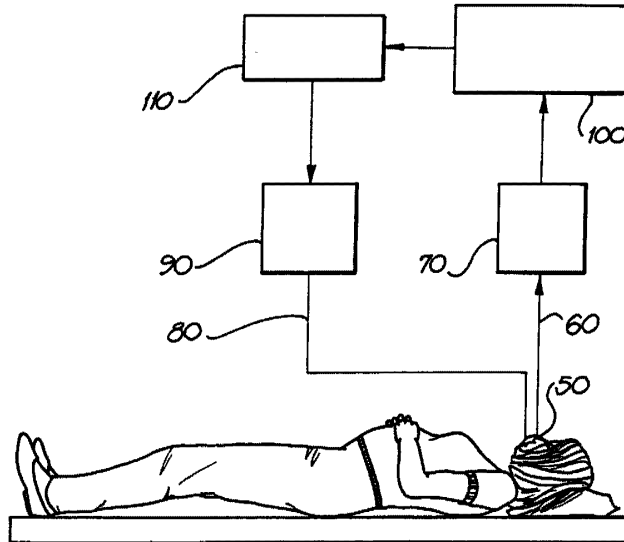
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(54) Title: APPARATUS AND METHOD FOR THE TREATMENT OF AN UPPER AIRWAY FLOW LIMITATION



(57) Abstract: An apparatus and a method for the treatment of an upper airway flow limitation, the apparatus including a means to detect an interruption in an upper airway inspiratory flow rate of the patient and further including a treatment means which treats the upper airway flow limitation on detection of the interruption cycle.

**APPARATUS AND METHOD FOR THE TREATMENT OF AN UPPER  
AIRWAY FLOW LIMITATION**

**Technical Field**

5           The present invention concerns an apparatus and method for the treatment of an upper airway flow limitation in a patient. In particular, the present invention concerns an apparatus and method of treating hypertension caused by pre-eclampsia.

**Background**

10           Hypertension in pregnancy is associated with increased risk of foetal growth retardation and in severe cases can lead to both maternal and foetal problems. It is the major complication of pregnancy and is one of the three leading causes of maternal death.

15           Hypertension in pregnant women is either a chronic condition caused by a disease unrelated to pregnancy (essential or secondary hypertension), or caused by a pregnancy induced condition known as "pre-eclampsia" (also known as "pregnancy induced hypertension"). In the former condition, elevated blood pressure is the cardinal patho-physiological feature. In pre-eclampsia, the increased blood pressure is a sign of the underlying disorder  
20           and the impact of the two conditions and their management on the mother and foetus is quite different. An attempt to differentiate these two classes of patient has led to confusion in terminology worldwide.

25           The circadian blood pressure (BP) variation in normal pregnancy is similar to that of non-pregnant women, with the highest value being in the morning and the lowest around midnight. A similar pattern exists in pregnancy accompanied by chronic (essential) hypertension.

          In contrast, in women with pre-eclampsia, the diurnal blood pressure pattern is reversed with the maximum blood pressure occurring at night.

30           Pre-eclampsia is a disease of the placenta with widespread systemic effects affecting maternal renal, cerebral, hepatic and/or clotting functions. The principal clinical features include hypertension, proteinuria and oedema with any or all of these present.

35           While there are generally agreed risk factors for pre-eclampsia, the precise causes and mechanisms remain unproved. In addition, there are no clear indicators that are useful in predicting the occurrence or the severity of the condition. There are no known effective preventative measures and

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although various techniques and medications are used to limit the symptoms (in particular the hypertension), the only definitive treatment is delivery of the baby, and removal of the diseased placenta.

5 Pre-eclampsia usually occurs after 20 weeks gestation and most frequently near term. Pre-eclampsia (and the hypertension associated with it) is a different medical condition to essential or secondary hypertension (e.g., as illustrated by the different diurnal characteristics). The methods used to manage patients with pre-eclampsia mainly consist of closely monitoring the patient and if necessary, controlling blood pressure with medication. In severe cases, additional medications are used to prevent convulsions (eclampsia).

10 It has been recognised that obstructive sleep apnea (OSA) is related to elevated blood pressure. The inventor has previously demonstrated the treatment of OSA by use of Continuous Positive Airway Pressure (CPAP), and in particular nasal-Continuous Positive Airway Pressure (nCPAP). It has also been demonstrated that partial airflow limitation (upper airway resistance syndrome "UARS") can cause elevations in blood pressure and that the blood pressure can be controlled by the use of CPAP, and in particular nCPAP. However patients with pre-eclampsia-induced hypertension may not display symptoms indicative of UARS. Accordingly, UARS symptoms in such a patient may be missed resulting in the hypertension caused by pre-eclampsia going untreated.

### Summary of the Invention

25 In a first aspect, the present invention consists in an apparatus for the treatment of an upper airway flow limitation in a patient, the apparatus including;

30 a means to detect at least one interruption cycle in an upper airway inspiratory flow rate of the patient wherein the interruption cycle is characterised by a decrease in upper airway inspiratory flow rate followed by an increase in the upper airway inspiratory flow rate; and

a treatment means which treats the upper airway flow limitation on detection of said at least one interruption cycle in the upper airway inspiratory flow rate.

In one embodiment, the detection means of the apparatus is adapted to detect a plurality of interruption cycles in the upper airway inspiratory flow rate.

5 In a further embodiment, the interruption cycle is indicative of an upper airway flow limitation.

In a further embodiment, the detection means detects a decrease in the inspiratory flow rate followed by a subsequent increase in inspiratory flow rate. In this embodiment, the flow rate is interrupted, and the flow rate decreases, followed by a recovery whereupon the flow rate increases before the flow rate finally decreases towards the end of inspiration.

In another embodiment, the subsequent increase in inspiratory flow rate increases the inspiratory flow rate to a maxima that is substantially the same as the rate before the decrease in inspiratory flow rate.

15 In a further embodiment, the subsequent increase in inspiratory flow rate increases the inspiratory flow rate to a maxima that is relatively lesser rate than the rate before the decrease in inspiratory flow rate.

In yet a further embodiment, the subsequent increase in inspiratory flow rate increases the inspiratory flow rate to a maxima that is relatively greater rate than the rate before the decrease in inspiratory flow rate.

20 In a still further embodiment, the detection means is adapted to detect the occurrence of at least two or more interruption cycles in the upper inspiratory flow rate and the treatment means treats the airway limitation on detection of said at least two interruption cycles.

In another embodiment, the apparatus is used in the treatment of hypertension caused by pre-eclampsia. In this embodiment, the interruption to inspiratory flow rate is indicative of an upper airway flow limitation which can lead to pre-eclampsia induced hypertension. The type of interruption cycle detected may not be observed in a breathing pattern of a patient suffering from another form of airway limitation such as snoring or sleep apnea. While there is still an inspiratory airway flow limitation in a patient suffering from another form of airway limitation, the increase in airway flow following a decrease in airway flow is not observed. Instead, the inspiratory flow rate continues to decrease at a certain rate until inspiration ends and expiration begins.

35 In a further embodiment of the first aspect of the invention, the detection means includes a means for measuring vibrations in a patient's

airway. Preferably, the detection means to detect the at least one interruption cycle further includes an identification means for identifying those measured airway vibrations which are indicative of the upper airway flow limitation.

5           In a further embodiment, the measured vibrations in the patient's airway indicative of upper airway flow limitation are caused by a decrease in the diameter of the airway followed by a subsequent increase in the diameter of the airway.

10           In another embodiment, the subsequent increase in diameter of the airway increases the diameter to substantially the same diameter as before the decrease in diameter of airway.

          In a further embodiment, the subsequent increase in diameter of the airway increases the diameter to a diameter less than the diameter before the initial decrease in diameter of the airway.

15           In a further embodiment, the subsequent increase in diameter of the airway increases the diameter to a diameter greater than the diameter before the initial decrease in diameter of the airway.

          In a second aspect, the present invention consists in an apparatus when used in the treatment of hypertension caused by pre-eclampsia, the apparatus including:

20           a flow rate measurement means which measures an air flow intake rate in an airway of a patient; and

25           a treatment means which treats an upper airway flow limitation in the patient when the measured air flow intake rate falls below a pre-determined flow rate to alleviate hypertension caused by pre-eclampsia.

          In a third aspect, the present invention consists in an apparatus for the treatment of hypertension caused by pre-eclampsia, the apparatus including:

          a measuring means for measuring airway vibrations in a patient;

30           an identification means which identifies those measured airway vibrations which are indicative of an upper airway flow limitation; and

          a treatment means which treats the upper airway flow limitation in the patient.

          In one embodiment of the third aspect, the apparatus is used for the treatment of hypertension caused by pre-eclampsia.

35           In a fourth aspect, the present invention consists in a method of treating an upper airway flow limitation in a patient including the steps of:

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