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WO 02/26315 A1

(54) Title: MINIMALLY INVASIVE SURGERY PLACEMENT OF STIMULATION LEADS IN MEDIASTINAL STRUCTURES

(57) Abstract: A method for placement of electrostimulation leads in the mediastinum is provided. More particularly, this invention relates to placement of electrostimulation leads in the mediastinum using minimally invasive surgical techniques. Leads so placed may be used to stimulate specific mediastinal organs including, for example, the esophagus, neural structures such as the vagus and phrenic nerves, and cardiovascular organs such as the heart and other vessels in order to provide therapeutic, physiological, and/or pathophysiological effects on the mediastinal organs and/or target organs to which such mediastinal organs or structures are attached.

MINIMALLY INVASIVE SURGERY PLACEMENT OF STIMULATION LEADS IN MEDIASTINAL STRUCTURES

CROSS-REFERENCE TO RELATED APPLICATION

This application claims the benefit of U.S. Provisional
5 Application No. 60/235,659, filed September 26, 2000.

FIELD OF THE INVENTION

The invention relates to placement of electrostimulation leads in the
mediastinum. More particularly, this invention relates to placement of
electrostimulation leads in the mediastinum using minimally invasive surgical
10 techniques. Leads so placed may be used to stimulate specific mediastinal
organs including, for example, the esophagus, neural structures such as the
vagus and phrenic nerves, and cardiovascular organs such as the heart and
other vessels in order to provide therapeutic, physiological, and/or patho-
physiological effects on the mediastinal organs and/or target organs to which
15 such mediastinal organs or structures are attached.

SUMMARY OF THE INVENTION

The invention relates to placement of electrostimulation leads in the
mediastinum. More particularly, this invention relates to placement of
electrostimulation leads in the mediastinum using minimally invasive surgical
20 techniques. Leads so placed may be used to stimulate specific mediastinal
organs including, for example, the esophagus, neural structures such as the
vagus and phrenic nerves, and cardiovascular organs such as the heart and
other vessels in order to provide therapeutic, physiological, and/or patho-
physiological effects on the mediastinal organs and/or target organs to which
25 such mediastinal organs or structures are attached.

In one embodiment, suitable minimally invasive surgical instruments
are used to gain access to the desired mediastinum organs by insertion from
the abdominal skin under the rib cage, preferably in the area of the xiphoid.

Such an approach avoids violating the pleural space. Alternatively, the desired mediastinum organs may be approached from the cervical region and through the superior mediastinum and using a cephalad caudal direction.

DESCRIPTION OF THE DRAWINGS

5 Figure 1 generally illustrates the vagus nerve and the mediastinal organs innervated by the vagus nerve. The branches 10 of the vagus nerve leading to, or adjacent to, the stomach which are especially useful with electrostimulation techniques for treatment of obesity are highlighted.

 Figure 2 generally illustrates the torso with the xyphoid or xyphoid
10 process 20 highlighted. In one embodiment of the present invention, suitable minimally invasive surgical instruments are used to gain access to the desired mediastinum organs by insertion from the abdominal skin under the rib cage, preferably in the area of the xyphoid 20 as highlighted by area 21. Such an approach avoids violating the pleural space. Alternatively, the
15 desired mediastinum organs may be approached from the cervical region and through the superior mediastinum using a cephalad caudal direction; this approach can be implemented using, for example, trocars 23.

 Figure 3 also illustrates the torso with the xyphoid or xyphoid process
20 20 highlighted. In one embodiment of the present invention, suitable minimally invasive surgical instruments are used to gain access to the desired mediastinum organs by insertion from the abdominal skin under the rib cage as generally illustrated by arrow 22. Alternatively, the desired mediastinum organs may be approached from the cervical region and through the superior mediastinum using a cephalad caudal direction as generally illustrated by
25 arrow 24.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

The invention relates to placement of electrostimulation leads in the mediastinum. More particularly, this invention relates to placement of

electrostimulation leads in the mediastinum using minimally invasive surgical techniques. Leads so placed may be used to stimulate specific mediastinal organs including, for example, the esophagus, neural structures such as the vagus and phrenic nerves, and cardiovascular organs such as the heart and
5 other vessels in order to provide therapeutic, physiological, and/or pathophysiological effects on the mediastinal organs and/or target organs to which such mediastinal organs or structures are attached.

In one embodiment, suitable minimally invasive surgical instruments are used to gain access to the desired mediastinum organs by insertion from
10 the abdominal skin under the rib cage, preferably in the area of the xyphoid. Such an approach avoids violating the pleural space. Alternatively, the desired mediastinum organs may be approached from the cervical region and through the superior mediastinum using a cephalad caudal direction.

The present invention is especially adapted for placement of
15 electrostimulation leads onto the vagus nerve and more preferably on the branches of the vagus nerve feeding the esophagus or the stomach. Placement of such electrostimulation leads on vagus nerve, or branches of the vagus nerve, leading to, or adjacent to, the stomach can be used with electrostimulation techniques for treatment of obesity. Reference 10 in
20 Figure 1 generally illustrates the portion of the vagus nerve especially adapted for electrostimulation for inducing weight loss in a human subject, including the control or treatment of obesity.

The present invention generally uses convention minimally invasive surgical techniques to place the desired electrostimulation device on or
25 adjacent to the specific mediastinal organ or organs desired to be stimulated. Conventional electrostimulation devices may be used in the practice of this invention. Such devices include, for example, those described in U.S. Patent 5,423,872 (June 3, 1995) (an implantable gastric electrical stimulator at the antrum area of the stomach which generates sequential electrical pulses to
30 stimulate the entire stomach, thereby artificially altering the natural gastric

motility to prevent emptying or to slow down food transit through the stomach); U.S. Patent 5,690,691 (November 25, 1997) (a portable or implantable gastric pacemaker employing a number of electrodes along the greater curvature of the stomach for delivering phased electrical stimulation at different locations to accelerate or attenuate peristaltic movement in the GI tract); U.S. Patent 5,836,994 (November 17, 1998) (an implantable gastric stimulator which incorporates direct sensing of the intrinsic gastric electrical activity by one or more sensors of predetermined frequency bandwidth for application or cessation of stimulation based on the amount of sensed activity); U.S. Patent 5,861,014 (January 19, 1999) (an implantable gastric stimulator for sensing abnormal electrical activity of the gastrointestinal tract so as to provide electrical stimulation for a preset time period or for the duration of the abnormal electrical activity to treat gastric rhythm abnormalities); U.S. Patent 6,041,258 (March 21, 2000) (electrostimulation device with improved handle for laparoscopic surgery); U.S. Patent Application Serial Number 09/640,201 (filed August 16, 2000) (eletrostimulation device attachable to enteric or endo-abdominal tissue or viscera which is resistance to detachment); PCT Application Serial Number _____ (filed _____; Attorney Docket No. 3581/006 PCT) entitled "Gastric Stimulator Apparatus and Method for Installing" based on United States Provisional Application Serial Numbers 60/129,198 and 60/129,199 (both filed April 14, 1999); PCT Application Serial Number _____ (filed _____; Attorney Docket No. 3581/004 PCT) entitled "Gastric Stimulator Apparatus and Method for Use" based on United States Provisional Application Serial Numbers 60/129,209 (filed April 14, 1999) and 60/466,387 (filed December 17, 1999); and U.S. Provisional Patent Application Serial Number _____ (filed the same date as the present application) entitled "Method and Apparatus for Intentional Impairment of Gastric Motility and/or Efficiency by Triggered Electrical Stimulation of the Gastric Tract with Respect to the Intrinsic Gastric Electrical Activity." All of these patents, patent applications,

provisional patent applications, and/or publications are hereby incorporated by reference.

CLAIMS

We claim:

1. A method for stimulating mediastinum tissue, said method comprising

(1) inserting an electrostimulation device under skin and accessing the mediastinum tissue to be stimulated, wherein the electrostimulation device has an electrostimulation lead and a distal end;

(2) attaching the electrostimulation lead to the mediastinum tissue to be stimulated;

(3) attaching the proximal end to a pulse generator; and

(3) using the pulse generator to deliver electrical stimulation through the electrostimulation lead to the mediastinum tissue to be stimulated,

wherein the insertion of the electrostimulation device and attachment of the electrostimulation lead are implemented using minimally invasive surgical techniques.

2. The method of claim 1, wherein mediastinum tissue to be treated is vagus nerve or a branch of the vagus nerve.

3. The method of claim 1, wherein mediastinum tissue to be treated is vagus nerve or a branch of the vagus nerve leading to the stomach.

4. The method of claim 1, wherein the pulse generator is an implantable and programmable pulse generator.

5. The method of claim 2, wherein the pulse generator is an implantable and programmable pulse generator.

6. The method of claim 3, wherein the pulse generator is an implantable and programmable pulse generator.

7. The method of claim 1, wherein the mediastinum tissue is accessed from abdominal skin and under rib cage.

8. The method of claim 7, wherein the abdominal skin is adjacent to xyphoid.

9. The method of claim 2, wherein the mediastinum tissue is accessed from abdominal skin and under rib cage.

10. The method of claim 9, wherein the abdominal skin is adjacent to xyphoid.

11. The method of claim 3, wherein the mediastinum tissue is accessed from abdominal skin and under rib cage.

12. The method of claim 11, wherein the abdominal skin is adjacent to xyphoid.

13. The method of claim 1, wherein the mediastinum tissue is accessed from cervical region and through superior mediastinum using a cephalad caudal direction.

14. The method of claim 2, wherein the mediastinum tissue is accessed from cervical region and through superior mediastinum using a cephalad caudal direction.

15. The method of claim 3, wherein the mediastinum tissue is accessed from cervical region and through superior mediastinum using a cephalad caudal direction.

16. A method of inducing weight loss in a human subject, said method comprising:

(1) inserting an electrostimulation device under skin and accessing the mediastinum tissue to be stimulated, wherein the electrostimulation device has an electrostimulation lead and a distal end;

(2) attaching the electrostimulation lead to the mediastinum tissue to be stimulated;

(3) attaching the proximal end to an implantable programmable pulse generator; and

(4) using the pulse generator to deliver electrical stimulation through the electrostimulation lead to the mediastinum tissue to be stimulated,

wherein the insertion of the electrostimulation device and attachment of the electrostimulation lead are implemented using minimally invasive surgical techniques.

17. The method of claim 16, wherein mediastinum tissue to be treated is vagus nerve or a branch of the vagus nerve.

18. The method of claim 16, wherein the mediastinum tissue is accessed from abdominal skin and under rib cage.

19. The method of claim 18, wherein the abdominal skin is adjacent to xyphoid.

20. The method of claim 17, wherein the mediastinum tissue is accessed from abdominal skin and under rib cage.

21. The method of claim 20, wherein the abdominal skin is adjacent to xyphoid.

22. The method of claim 16, wherein the mediastinum tissue is accessed from cervical region and through superior mediastinum using a cephalad caudal direction.

23. The method of claim 17, wherein the mediastinum tissue is accessed from cervical region and through superior mediastinum using a cephalad caudal direction.

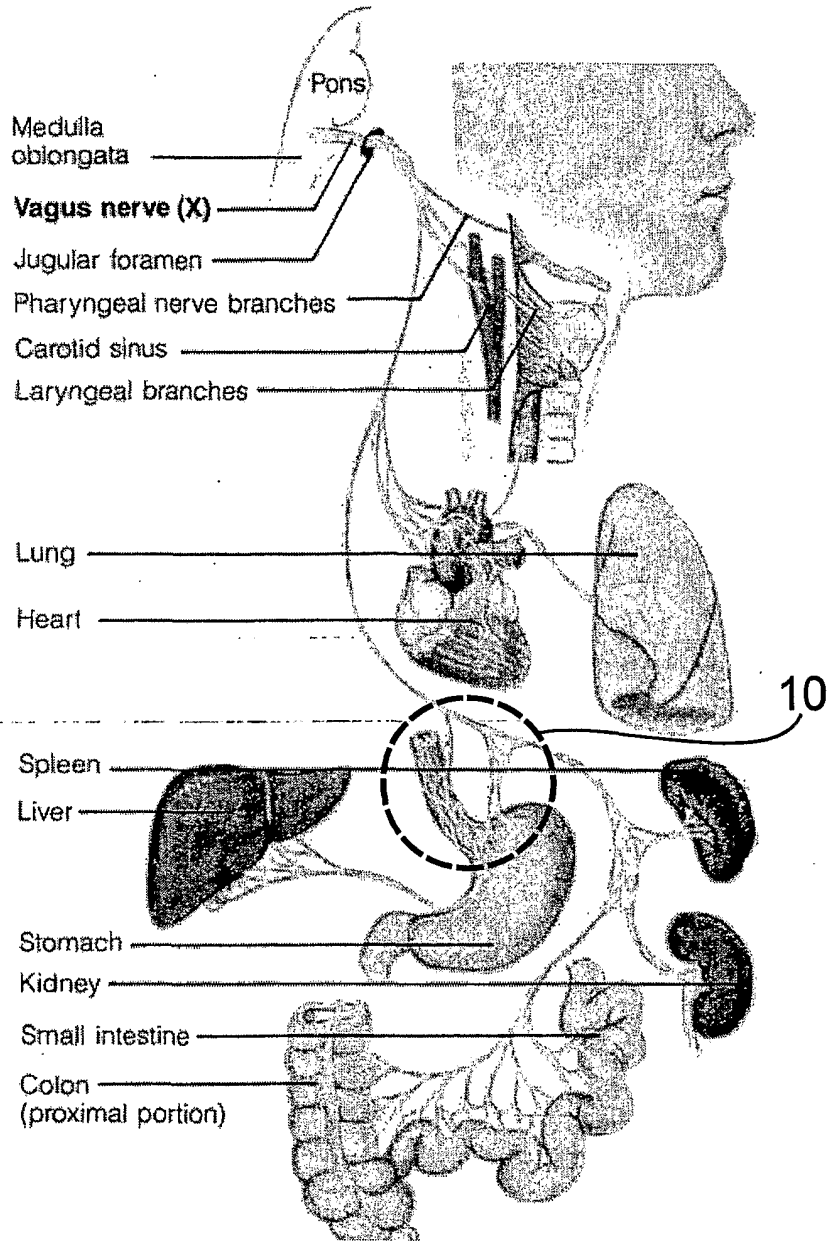
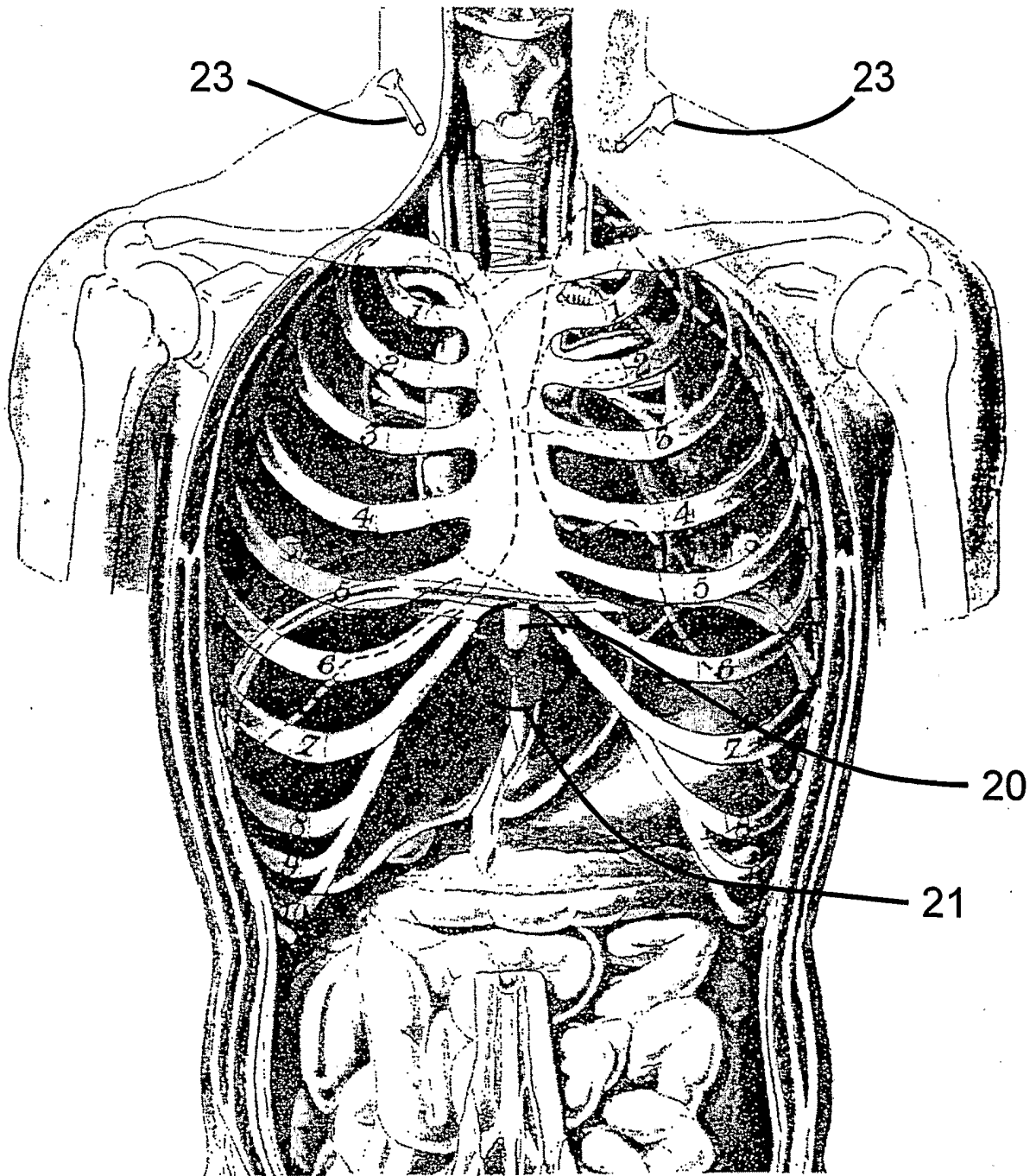


Figure 1



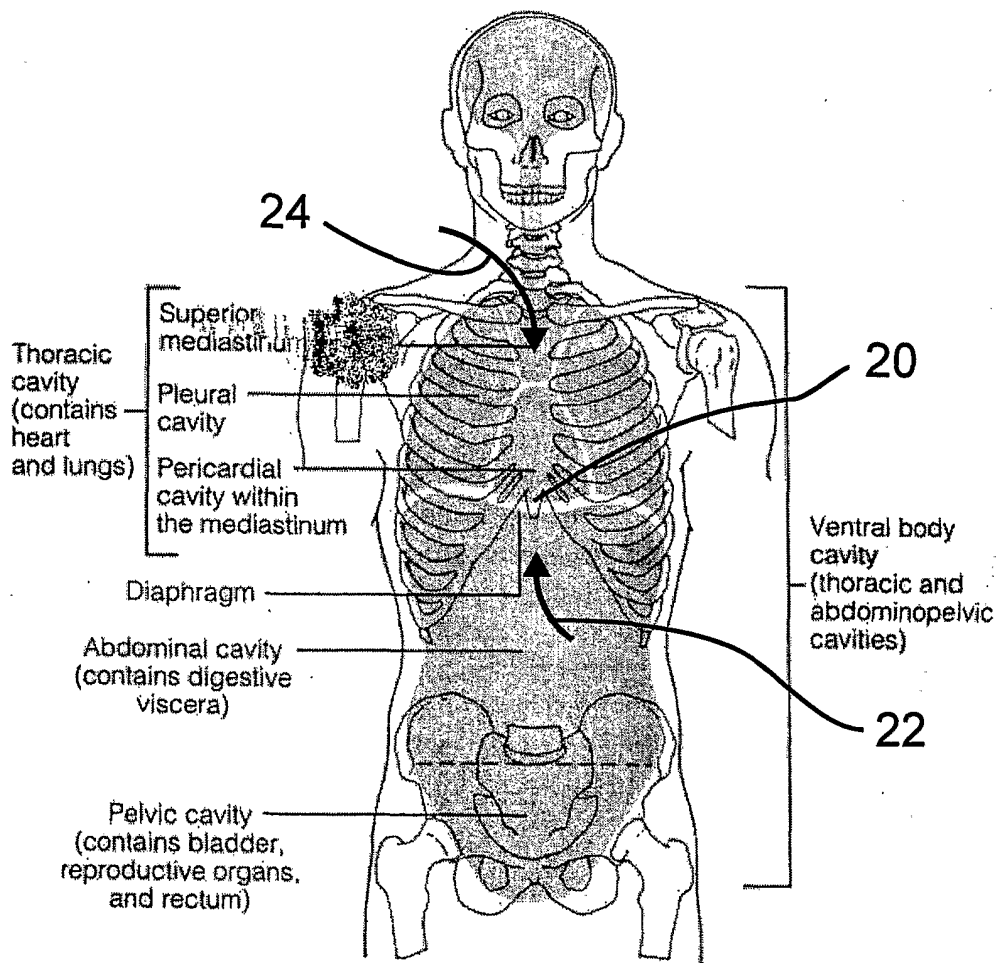


Figure 3

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US01/29914

A. CLASSIFICATION OF SUBJECT MATTER

IPC(7) :A61N 1/18

US CL :607/40

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 607/40, 118, 133; 600/373

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 6,026,326 A (BARDY) 15 February 2000, Abstract, figure 1 and column 13, lines 28-29.	1-6, 7, 9, 11
X	US 5,861,014 A (FAMILONI) 19 January 1999, Abstract.	1-6
Y	US 5,540,734 A (ZABARA) 30 July 1996, Abstract and column 4, lines 61-65.	13-15
X	US 5,540,730 A (TERRY et al) 30 July 1996, Abstract, figure 3 and column 5, lines 19-38.	1-6, 7, 9, 11
X	US 5,188,104 A (WERNICKE et al) 23 February 1993, Summary of Invention.	1-6, 7-12, 16-21

Further documents are listed in the continuation of Box C.

See patent family annex.

* Special categories of cited documents:	"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"A" document defining the general state of the art which is not considered to be of particular relevance	"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
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