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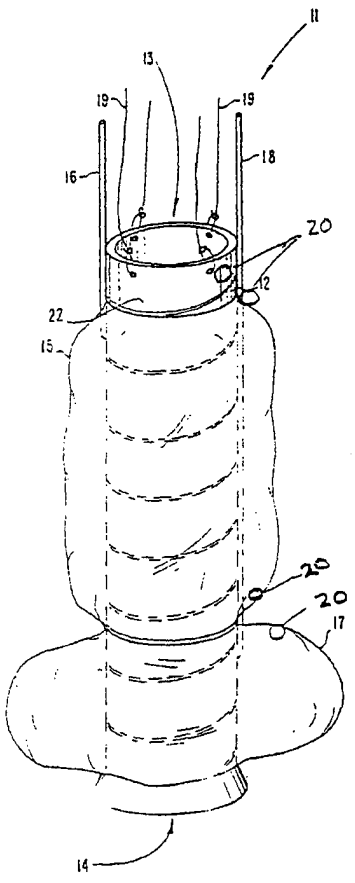
(54) Title: APPARATUS AND METHOD FOR CONTINUOUS MEASUREMENT OF PORTAL BLOOD PRESSURE



(57) Abstract: A method and a device for the intermittent or continuous measurement of portal blood pressure using a tamponade balloon inserted into the esophagus and stomach and a sensor positioned on the bridle, tamponade shaft or esophageal balloon. The tamponade balloons mounted over a tube are placed across the diaphragmatic hiatus and are gradually inflated through a lumen that runs from the balloons to a position that is external from the patient. The measured pressure within the tamponade is increased until the blood flow in the collateral portal hepatic veins that traverse the diaphragm is blocked. The cessation of the blood flow into the esophageal varices is signaled when the sensor identifies a change in diameter of the varices, a change in the color of the esophageal wall, or a change in velocity of blood flow. The measured tamponade pressure at the nadir of variceal blood flow is equivalent to portal blood pressure.

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For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

APPARATUS AND METHOD FOR CONTINUOUS MEASUREMENT OF PORTAL BLOOD PRESSURE

BACKGROUND OF THE INVENTION

1. Field of the Invention

This invention pertains to a method and a device for the continuous measurement of portal blood pressure. The method and device use an inflatable balloon inserted into the stomach and esophagus with a sensor to monitor the portal blood pressure.

2. The Prior Art

U.S. Patent No. 5,653,240 to Zimmon, the disclosure of which is herein incorporated by reference, discloses a method and device for measuring portal blood pressure. That invention provides a tamponade device and a technically simple method for measuring portal venous pressure in patients with esophageal varices during upper gastrointestinal endoscopy. An advantage of the above mentioned invention is that it allows endoscopic surveillance of esophageal varices combined with measurement of portal venous pressure, particularly

during emergency therapy of variceal bleeding.

However, the use of a large endoscope such as used in the patent mentioned above to observe the collapse of esophageal varices is cumbersome and difficult for the patient, since it requires sedation. Further, the collapse and refilling of varices in the esophagus may be difficult to identify when varices are small or obscured by esophageal peristalsis and respiratory motion. It would be desirable to find a method for measuring portal blood pressure that eliminates the need for endoscopy and makes the use of tamponade with sensors available to those without endoscopic skills.

SUMMARY OF THE INVENTION

It is therefore an object of the present invention to provide a device and a technically simple method for the continuous measurement of portal pressure during balloon tamponade using sensors as alternatives to standard endoscopic techniques.

These and other objects are accomplished by a device for measuring portal blood pressure comprising a tube with proximal and distal open ends, an esophageal

inflatable balloon mounted over the tube, a first inflation lumen opening into the esophageal inflatable balloon for directing pressurized fluid to inflate the esophageal inflatable balloon, a gastric inflatable balloon mounted over the tube between the esophageal inflatable balloon and the distal open end, a second inflation lumen opening into the gastric inflatable balloon for directing pressurized fluid to inflate the gastric balloon, and a non-visual sensor mounted on the esophageal balloon or a small endoscope or video camera that is inserted through the tube, to detect the changes resulting from tamponade.

The invention also comprises a method of measuring the portal pressure by backloading the device on an endoscope by passing the endoscope through the open ends of the tube, passing the endoscope down the esophagus advancing the device along the endoscope and down the esophagus to a location within the diaphragmatic hiatus, positioning the gastric balloon inside the stomach and inflating the gastric balloon, pulling the balloon against the proximal stomach and the diaphragmatic hiatus with a traction means to seat the gastric balloon against

the gastric cardia, inflating the esophageal inflatable balloon to fix the device across the diaphragmatic hiatus by the two opposed balloons, releasing the traction means, locating the sensor to a position above or adjacent to the esophageal inflatable balloon, to observe esophageal varices, gradually inflating the balloons until blood flow in the portal veins traversing the diaphragmatic hiatus occludes, so that the esophageal varices collapse or blood flow ceases or is reduced to a nadir as detected by said sensor, and monitoring the pressure inside said esophageal inflatable balloon and gastric inflatable balloon as sensed by the sensor to obtain an indication of the portal blood pressure. Alternatively the tamponade device may be deployed over an oral-gastric tube to obviate the need for endoscopic equipment and endoscopic skills as described in US patent # 5,785,224, hereby incorporated by reference.

The device preferably also includes a bridle attached to the tube to extend up the esophagus to a traction means. The bridle is manipulated to position the proximal end of the device within the digestive tract and maintain the device in traction.

In addition, an aspiration tube is positioned within the stomach and a fluid supply tube is positioned adjacent to the esophageal balloon for coupling to the mucosal surface when an ultrasonic sensor is used.

For this purpose, deaerated fluid is gradually infused adjacent to the esophageal balloon while aspirating the stomach.

The stomach is aspirated and the fluid is infused adjacent to the esophageal balloon while deflating the esophageal inflatable balloon and gastric inflatable balloon until the esophageal varices distend or blood flow increases as determined by the sensor. The pressure within the balloons is then measured with a monometer or a second sensor.

Repeated measurements would be useful in monitoring portal pressure during the administration of drugs for the control of portal hypertension, particularly in patients with active or recent bleeding. The efficacy of drug therapy in reducing portal pressure must be determined to identify patients who can be spared other

interventions. Conversely, patients who fail to respond to drug therapy with a sufficient decrease in portal pressure, which reduces the risk of hemorrhage, would require alternative therapy.

Blood flow in esophageal varices is rapid and produces bulging blue visible vessels in the esophageal wall. A sensor that identifies a change in diameter of the varices, such as an ultrasound probe; a change in the color of the esophageal wall when the blue vessels diminish in size, such as reflectance spectrometry as in oximetry; or a change in velocity of flow as indicated by temperature, electrical impedance or doppler ultrasound, could be used.

Improvements in endoscopes have allowed the development of 2mm diameter battery powered endoscopes and small video cameras. Where electronic measurements or endoscopic ultrasound probes that require complex electrical monitoring devices are not available, a small endoscope or video camera can serve to identify varix collapse when placed through the patient's nose to the appropriate site above the tamponade. This endoscope

could be used in conjunction with the present invention to visualize whether the varices are expanded and visible or collapsed and tamponade pressure adjusted to obtain a pressure measurement. Similar periodic measurements would similarly be made using the sensors described.

The preferred method for measuring portal pressure would have a tamponade balloon such as that described in United States Patent No. 5,308,326, the disclosure of which is herein incorporated by reference, an expandable compression disc or other similar device located in the stomach and held in place by a similar device in the esophagus. A patent lumen connecting the esophagus and stomach to equalize pressure is important, since without such a lumen, swallowing and esophageal peristalsis periodically increases esophageal pressure to oppose variceal pressure and influences pressure and flow in esophageal varices.

A similar disability is present during routine endoscopic observation of varices in the esophagus since air inflation is essential to allow visualization of the varices. This is the distinct advantage of using a non-

visual sensor since air pressure would not be required.

The tamponade device must be provided with a bridle for introduction and communication with the balloon or compression discs as well as the sensor. This would be similar to the esophagogastric balloon tamponade device bridle described in US Patent No. 5,308,326, that is hereby incorporated by reference. With ultrasound or ultrasound doppler sensors, an additional source of fluid to couple the transducer to the esophageal wall is required. This is provided by a fine tube within or outside the bridle carrying a trickle of deaerated water or other fluid.

BRIEF DESCRIPTION OF THE DRAWINGS

Other objects and features of the present invention will become apparent from the following detailed description considered in connection with the accompanying drawings. It is to be understood, however, that the drawings are designed as an illustration only and not as a definition of the limits of the invention.

In the drawings, wherein similar reference characters denote similar elements throughout the several views:

FIG. 1 is a perspective view of one embodiment of a device used to practice this invention, for illustrative purposes, the full lengths of the wires 19 and of the lumens 16 and 18 are not shown; and

FIGS. 2 to 8 are step-by-step sectional views of the device illustrated in FIG. 1 being placed in a patient, according to one embodiment of this invention.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

Referring now in detail to the drawings and, in particular, FIG. 1 a preferred esophago-gastric balloon device 11 is shown. The device 11 includes an elongate member 12, preferably a tube, having a proximal end 13 and a distal end 14, where both ends are preferably open. An esophageal inflatable balloon 15 is mounted over the elongate member 12, and an inflation lumen 16 is provided for directing pressurized fluid in and out the esophageal inflatable balloon 15. A gastric inflatable balloon 17 is

mounted over the elongate member 12 and is adapted to seat against the gastric cardia when inflated in the stomach, and when the device 11 is pulled by the wires 19 in a direction up the esophagus. A separate inflation lumen 18 is provided to inflate and deflate the gastric inflatable balloon 17.

The esophageal inflatable balloon 15 is mounted over the elongate member 12. As to the method of mounting the esophageal inflatable balloon over the tube, it may be mounted by silk ties, bonding or vulcanizing, or any other suitable airtight manner known in the art. An inflation lumen 16 for directing pressurized fluid to inflate the esophageal inflatable balloon 15 is also provided and preferably is bonded to the side of the elongate member 12.

The gastric inflatable balloon 17 is mounted over the elongate member 12 near its distal end 14 to provide a seating surface within the stomach. The gastric inflatable balloon 17 has an inflated diameter which is sufficiently large, so that when positioned in the stomach and inflated, the gastric inflatable balloon 17

seats against and compresses the gastric cardia when the device 11 is pulled by the wires 19, or pulled by the proximal end of the elongate member 12 in a direction up the esophagus. The gastric inflatable balloon 17 can be mounted using silk ties, bonding or vulcanizing, or any other suitable airtight method known in the art.

A non-visual sensor 20 is mounted to one of balloons 15 and 17 for measuring the pressure. Sensor 20 can be any one of a variety of sensors, such as a sensor that identifies a change in diameter of the varices, such as an ultrasound probe; a change in the color of the esophageal wall when the blue vessels diminish in size, such as reflectance spectrometry as in oximetry; or a change in velocity of flow as indicated by temperature, electrical impedance or doppler ultrasound. Sensor 20 can be mounted in any of a variety of positions on the device, depending on the type of sensor to be used. The various positions of sensor 20 are shown in FIGS. 2-8.

An inflation lumen is also provided to direct pressurized fluid to inflate the gastric inflatable balloon 17. This lumen could be the same one which

inflates the esophageal inflatable balloon 15, but in a preferred device, a second and separate inflation lumen 18 is provided for the gastric inflatable balloon 17, and is also bonded to the side of the elongate member 12. The inflation lumen 18 passes through the esophageal inflatable balloon 15 and into the gastric inflatable balloon 17, opening only into the latter. This enables the selective inflation of the esophageal inflatable balloon 15 and the gastric inflatable balloon 17.

A preferred device 11 also includes a plurality of wires 19 which are attached to the elongate member 12 and generally form a bridle. In the preferred device 11, the wires 19 are of sufficient length that, when the device 11 is in place, the wires 19 extend up the esophagus and externally extend from the patient. Thus, the bridle is adapted and operable to allow the device 11 to be secured in place in the patient while having the proximal open end 13 of the elongate member 12 positioned within the esophagus. This provides a convenient passage through which materials may pass to the stomach and enables normal feeding and swallowing. The wires 19 are attached to the elongate member 12 by securing them through small

apertures 20 provided near the proximal open end 13 of the elongate member 12.

It is understood, however, that bonding or any other suitable means known in the art could be used to attach the wires 19 to the elongate member 12.

As an initial step to practice this invention, the device is passed down the esophagus, to a location within the patient's stomach. The device is backloaded on the endoscope or oral-gastric tube by passing the endoscope or oral-gastric tube through the open ends of the device. The endoscope or tube is then passed through the patient's mouth, down the esophagus, and into the stomach, usually a distance of about 50 cm past the patient's incisors.

Next and referring to FIG. 2, the device 11 is advanced by pushing with an overtube until the gastric inflatable balloon 17 is positioned within the stomach while leaving a portion of the bridle external to the patient.

Referring to FIG. 3, the gastric inflatable balloon 17 is inflated and the elongate member pulled with the bridle wires until the gastric inflatable balloon is felt to seat against the gastric cardia. Once in position, the pressure within the gastric inflatable balloon is preferably adjusted to about 50 mmHg.

Referring to FIG. 4, after the inflation of the gastric inflatable balloon 17 and its placement against the gastric cardia, the pushing tube is withdrawn from the stomach to a location above the device 11.

Referring to FIG. 5, the esophageal inflatable balloon 15 is then inflated to fix the device 11 into position by compressing the diaphragmatic hiatus and surrounding tissue. A preferable initial inflation pressure is about 50 mmHg. Once device 11 is fixed, the external pulling or traction to device 11 is then preferably released. The release of traction allows the patient's diaphragm to move in normal respiration which otherwise might prevent an accurate measure of the patient's portal blood pressure.

Once in position, the esophageal and gastric inflatable balloons are inflated and fixed into position by compressing the diaphragm and surrounding tissue from opposing sides of the diaphragm. The esophageal and gastric inflatable balloons are then further inflated and deflated, as needed, to measure portal blood pressure.

Additionally, prior to advancing the device down the esophagus, suitable hemostatic (such as microfibrillar collagen hemostat), coagulant (such as Thrombin, USP), or cytoprotective (such as sucralfate) substances can be applied to esophageal inflatable balloon 15 and/or gastric inflatable balloon 17. Such applications facilitate the later removal of the device by preventing adherence of the balloons to any bleeding sites. Referring to FIGS. 6 and 7, a preferred method for securing a bridle is shown. Once it has been confirmed that the device 11 is properly placed, a flexible guide tube having first and second open ends is provided. The first end of the guide tube is then placed through the nose and out the mouth of the patient, with the second end of the guide tube remaining external of the nose. Next, the bridle wires 19 and the inflation lumens 16 and

18, which are extending out of the mouth, are passed into said first end and out the second end of the guide tube. The guide tube is then withdrawn from the nose to leave bridle wires 19 and lumens 16 and 18 positioned through the patient's nose.

The established nasal bridle position is generally shown in FIG. 7. The gastric inflatable balloon 17 and the esophageal inflatable balloon 15 are inflated, and the wires 19 and the inflation lumens 16 and 18 are extending out of the nose. The appropriate connectors can then be placed on the inflation lumens 16 and 18 and the bridle wires 19 can be connected to a traction device as necessary. Having the lumens 16 and 18 and the bridle wires 19 positioned through the patient's nose increases patient comfort and reduces trauma to the nose and pharynx.

Referring to FIG. 8, the sensor measures the portal pressure as follows: pressure in the esophageal and gastric inflatable balloon is slowly reduced until the varices distend and reappear. Pressure is then increased in the esophageal and gastric inflatable balloon while

monitoring the inflation pressure. When the pressure inside the gastric inflatable balloon is high enough to occlude blood flow in the portal veins traversing the diaphragmatic hiatus, the varices above the esophageal inflatable balloon collapse. The balloon pressure required to occlude these portal collateral veins is about identical to the pressure in the main portal vein. Upon occlusion, the balloons may be deflated to allow the esophageal varices to distend and this pressure is also measured. The sensor identifies the change in diameter of the varices (using an ultrasound probe), a change in the color of the esophageal varices when the blue vessels diminish in size (using a reflectance spectrometry as in oximetry), or a change in velocity of flow as indicated by temperature or by using electrical impedance or doppler ultrasound. Sensor 20 is preferably mounted on the esophageal balloon. However, sensor 20 could also be mounted on the endoscope, tamponade shaft or bridle.

Although a balloon is the preferred embodiment of this invention, it must be understood that similar functions could be served by any type of compression device including a disc or cage activated by gas

pressure, a calibrated spring or any mechanical means.

Further details regarding the device can be found in Method and Device for Measuring Portal Blood Pressure, U.S. Patent No. 5,653,240 which is incorporated into this specification by reference.

Accordingly, while only one embodiment of the present invention has been shown and described, it is obvious that many changes and modifications may be made thereunto without departing from the spirit and scope of the invention.

WHAT IS CLAIMED IS:

1. A method for the continuous measurement of portal blood pressured, comprising the steps of:

providing a device having a tube with proximal and distal open ends, an esophageal inflatable balloon mounted over said tube, a first inflation lumen opening into said esophageal inflatable balloon for directing pressurized fluid to inflate said esophageal inflatable balloon, a gastric inflatable balloon mounted over said tube between said esophageal inflatable balloon and said distal open end, a second inflation lumen opening into said gastric inflatable balloon for directing pressurized fluid to inflate said gastric balloon, and a sensor attached to one of said balloons;

backloading said device on an endoscope, oral-gastric tube or other tube introducer by passing the introducer through said open ends of said tube;

passing the introducer down the esophagus;

advancing said device along the introducer with a pusher down the esophagus to a location within the

stomach;

positioning said gastric balloon inside the stomach and inflating said gastric balloon;

pulling said gastric balloon against the proximal stomach and the diaphragmatic hiatus with a traction means to seat said gastric balloon against the gastric cardia;

inflating the esophageal inflatable balloon to fix said device across the diaphragmatic hiatus by the two opposed balloons;

releasing said traction means;

locating said sensor to a position above or adjacent to the esophageal inflatable balloon, to monitor esophageal varices;

gradually inflating said balloons until blood flow in the portal veins traversing the diaphragmatic hiatus occludes, whereby the esophageal varices collapse

or blood flow ceases, or is reduced to a nadir as detected by said sensor; and

monitoring the pressure inside said esophageal inflatable balloon and said gastric inflatable balloon to obtain an indication of the portal blood pressure.

2. The method of claim 1, wherein said providing step further includes a bridle attached to said tube, said bridle adapted to extend up the esophagus to a traction means.

3. The method of claim 2, further comprising manipulating the bridle to position the proximal end of the member within the digestive tract and maintain the device in traction.

4. The method of claim 1, further comprising the step of positioning an aspiration tube within the stomach and a fluid supply tube adjacent to the esophageal balloon.

5. The method of claim 4, further comprising the

step of gradually infusing deaerated fluid adjacent to the esophageal balloon while aspirating the stomach.

6. The method of claim 1, further comprising aspirating the stomach and infusing the fluid adjacent to the esophageal balloon while deflating said esophageal inflatable balloon and said gastric inflatable balloon until the esophageal varices distend or blood flow increases as determined by said sensor and measuring the pressure within said balloons.

7. A device for continuously measuring portal blood pressure, comprising:

a tube with proximal and distal open ends,

an esophageal inflatable balloon mounted over said tube;

a first inflation lumen opening into said esophageal inflatable balloon for directing pressurized fluid to inflate said esophageal inflatable balloon;

a gastric inflatable balloon mounted over said

tube between said esophageal inflatable balloon and said distal open end;

a sensor mounted to one of said balloons; and

a second inflation lumen opening into said gastric inflatable balloon for directing pressurized fluid to inflate said gastric balloon.

8. The device according to claim 7, further comprising a traction means to seat said gastric balloon against the gastric cardia.

9. The device according to claim 8, further comprising a bridle attached to each balloon and adapted to extend up the esophagus to a traction means.

10. The device according to claim 7, further comprising a monitor connected to said sensor for monitoring the blood pressure sensed by said sensor.

11. The device according to claim 9, wherein the sensor is selected from the group consisting of an

ultrasound probe and an ultrasound doppler probe.

12. The device according to claim 11, further comprising a fine tube near the bridle carrying a trickle of deaerated water or other fluid across the sensor.

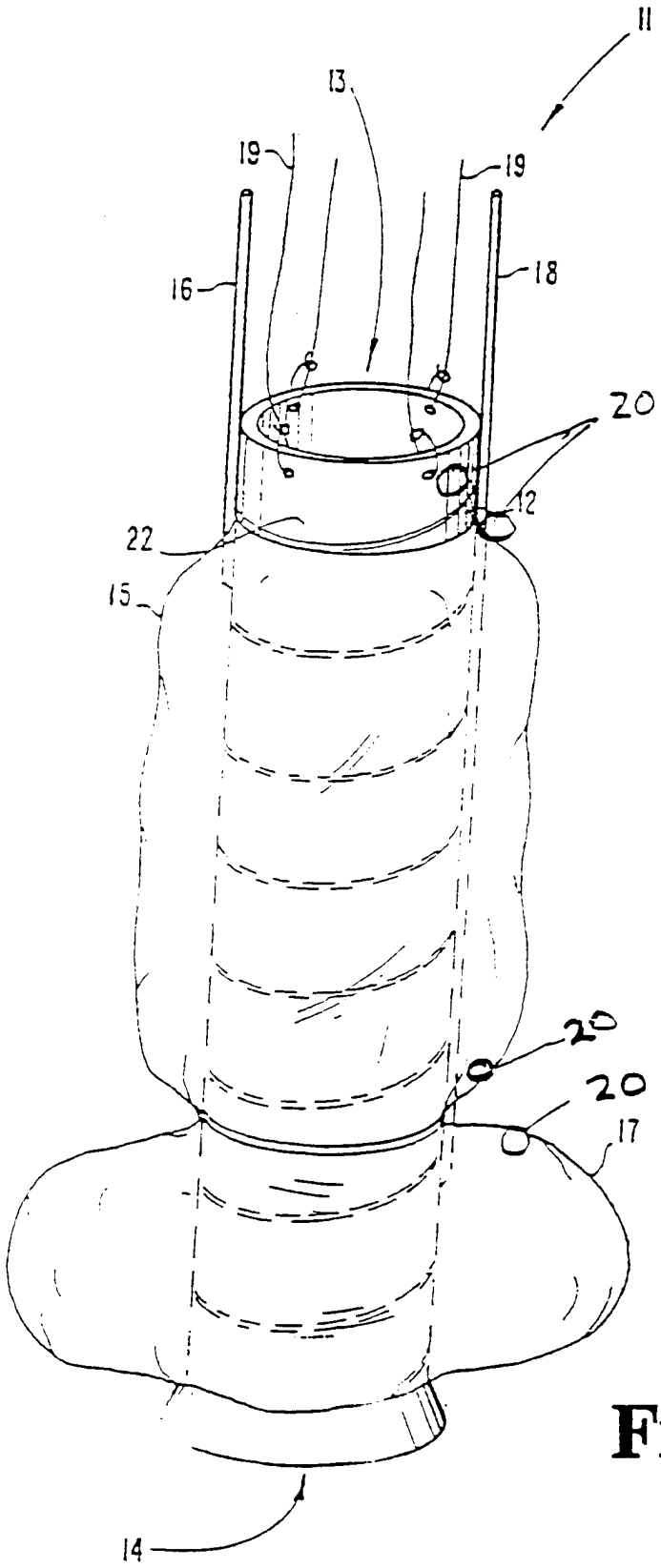

Fig. 1

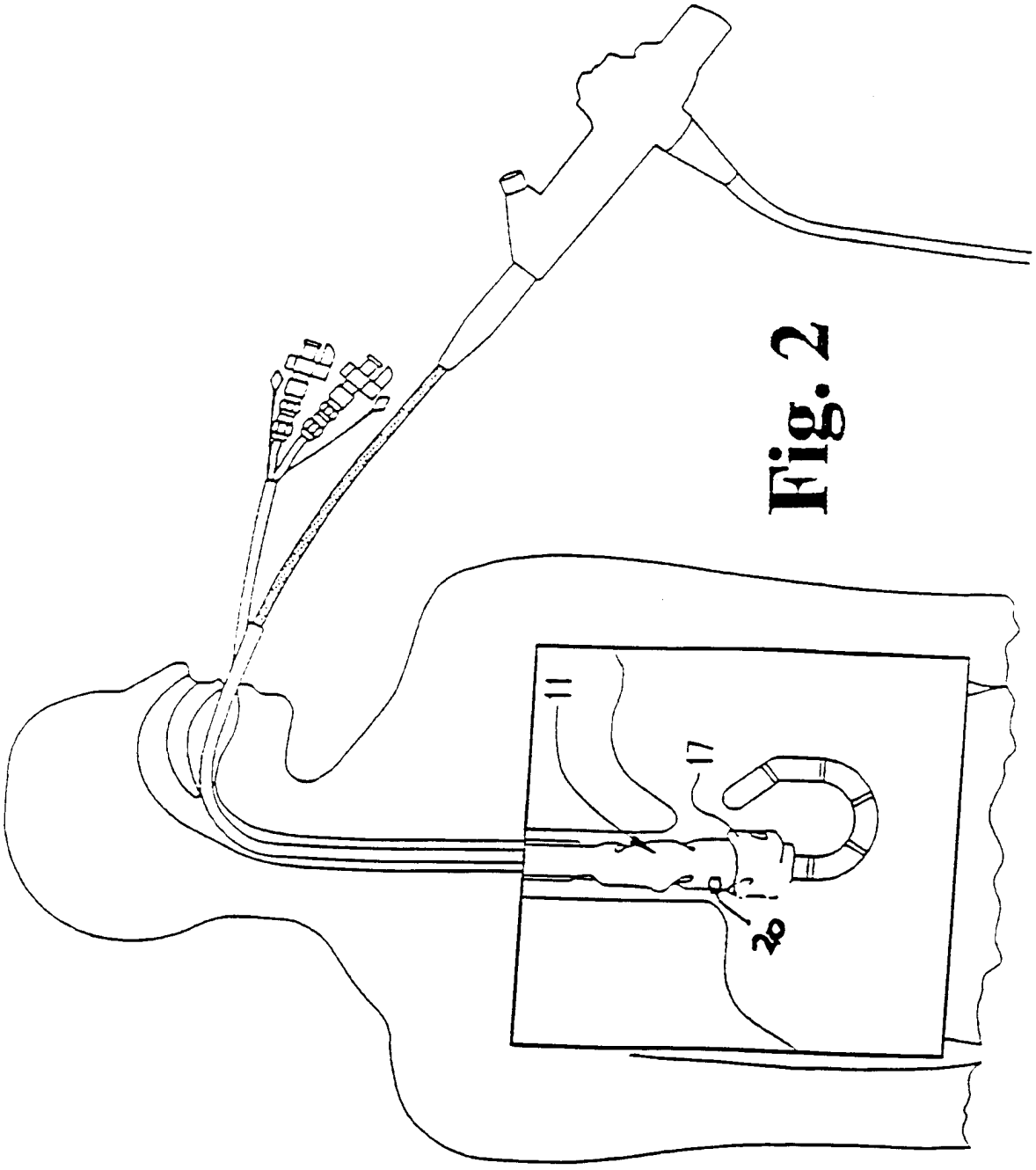

Fig. 2

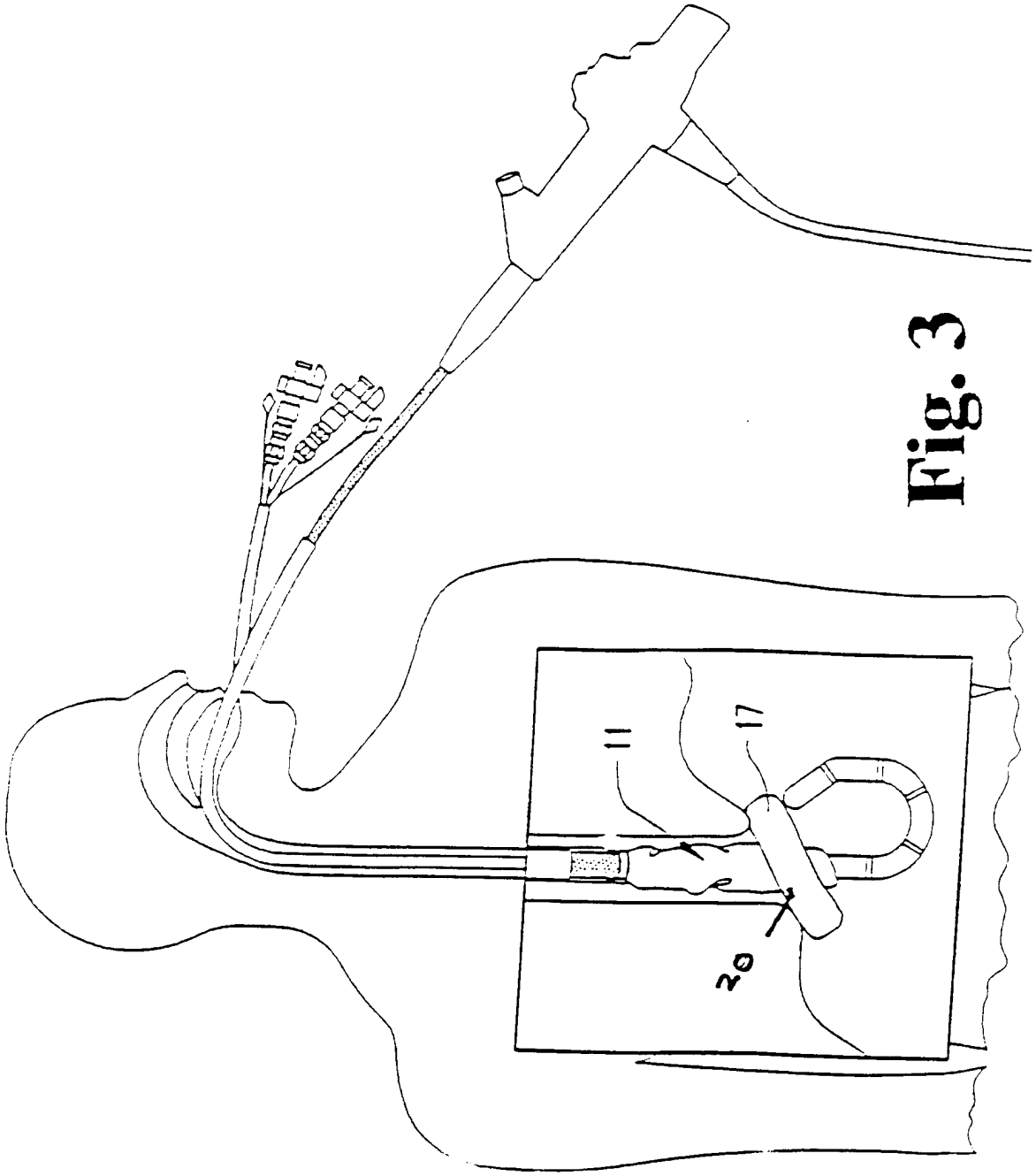

Fig. 3

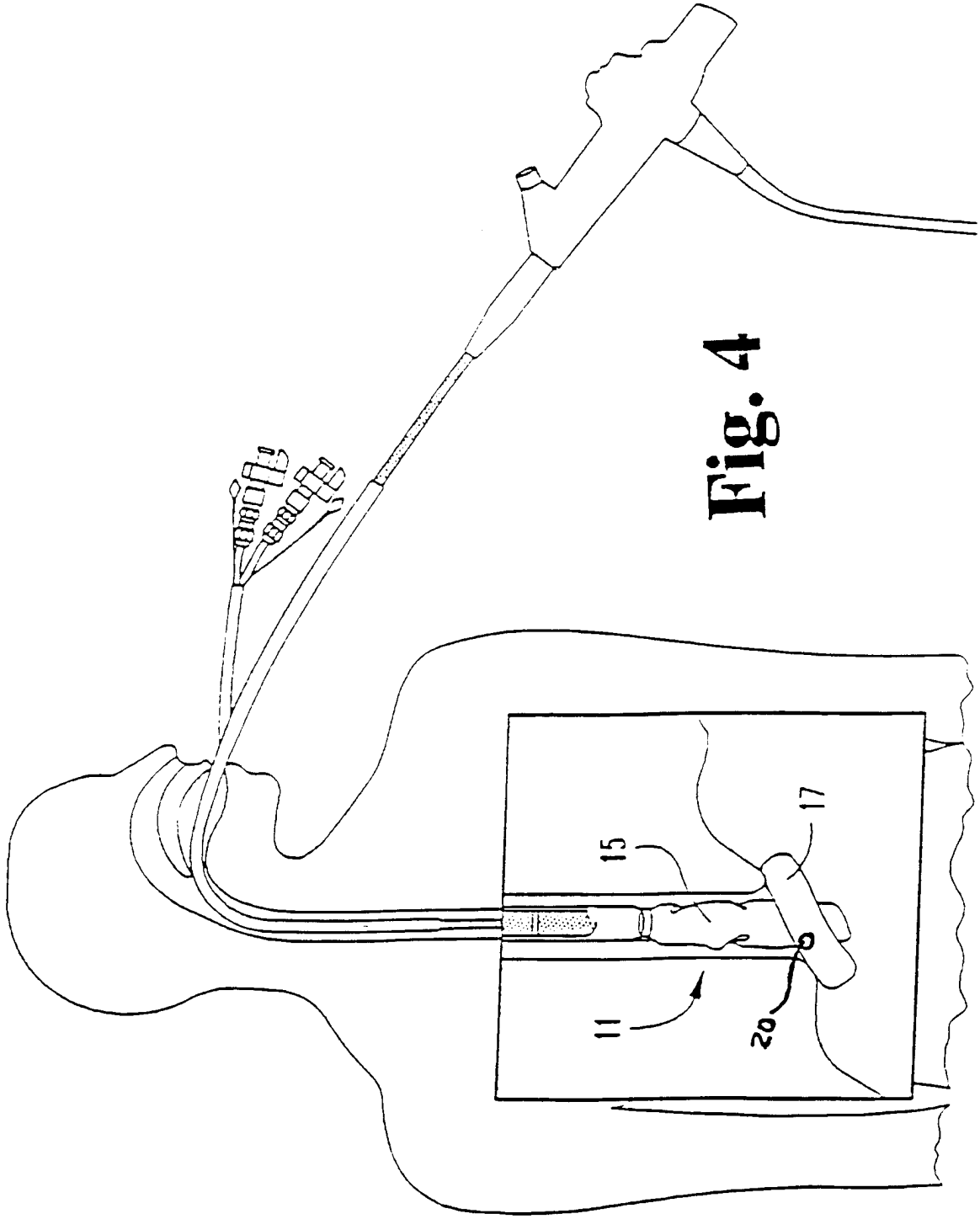

Fig. 4

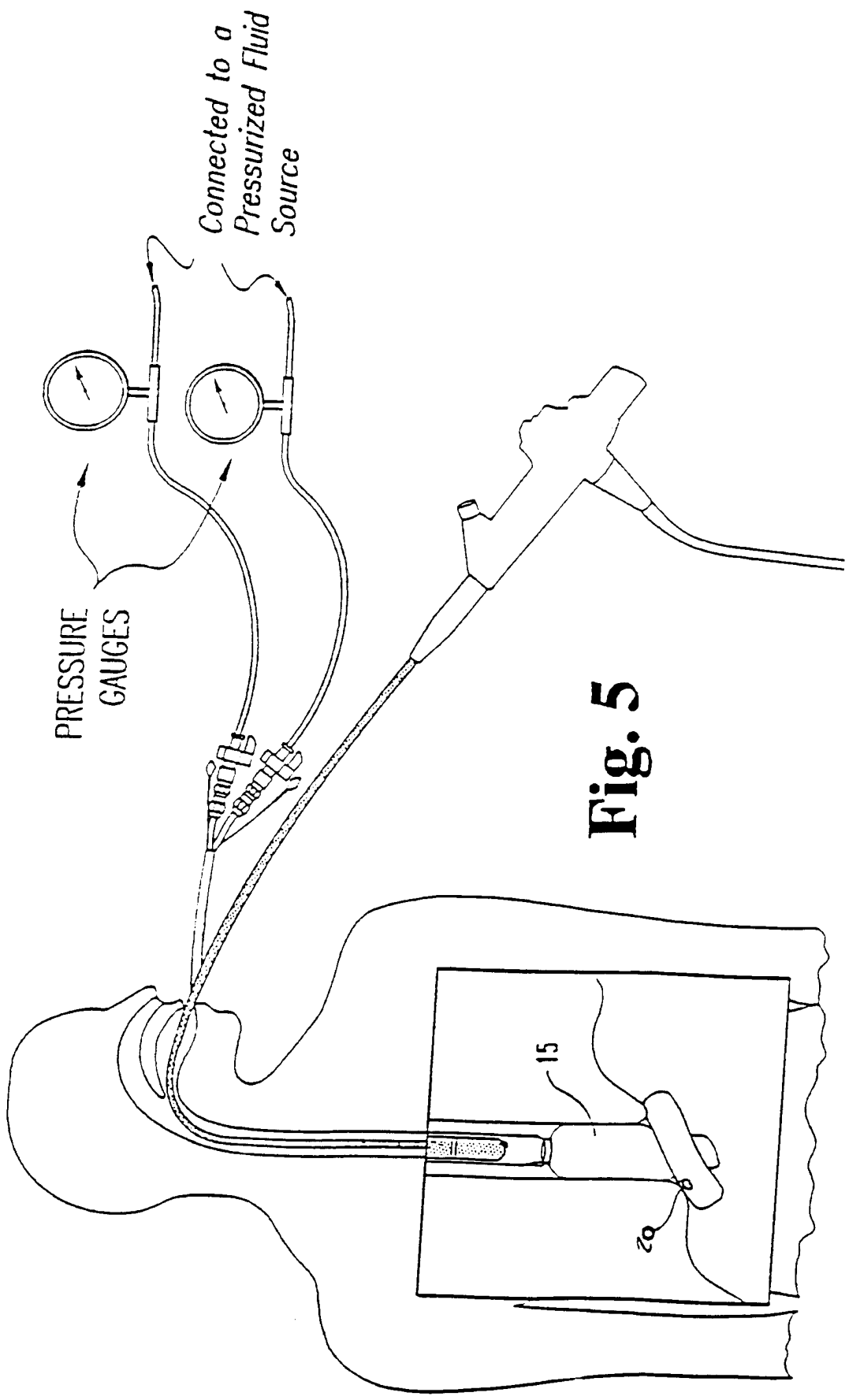
Connected to a Pressurized Fluid Source
PRESSURE GAUGES
15
20

Fig. 5

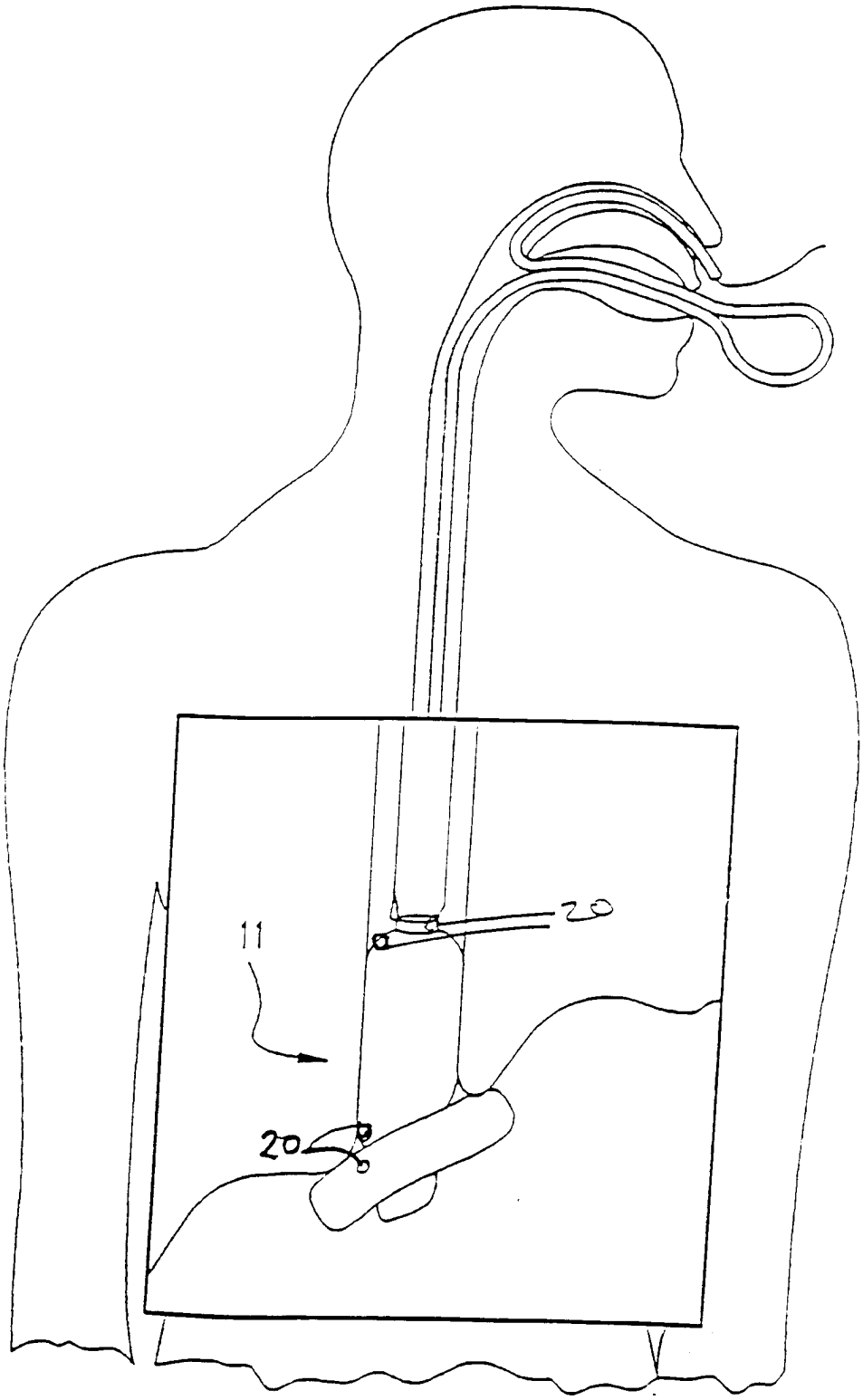

Fig. 6

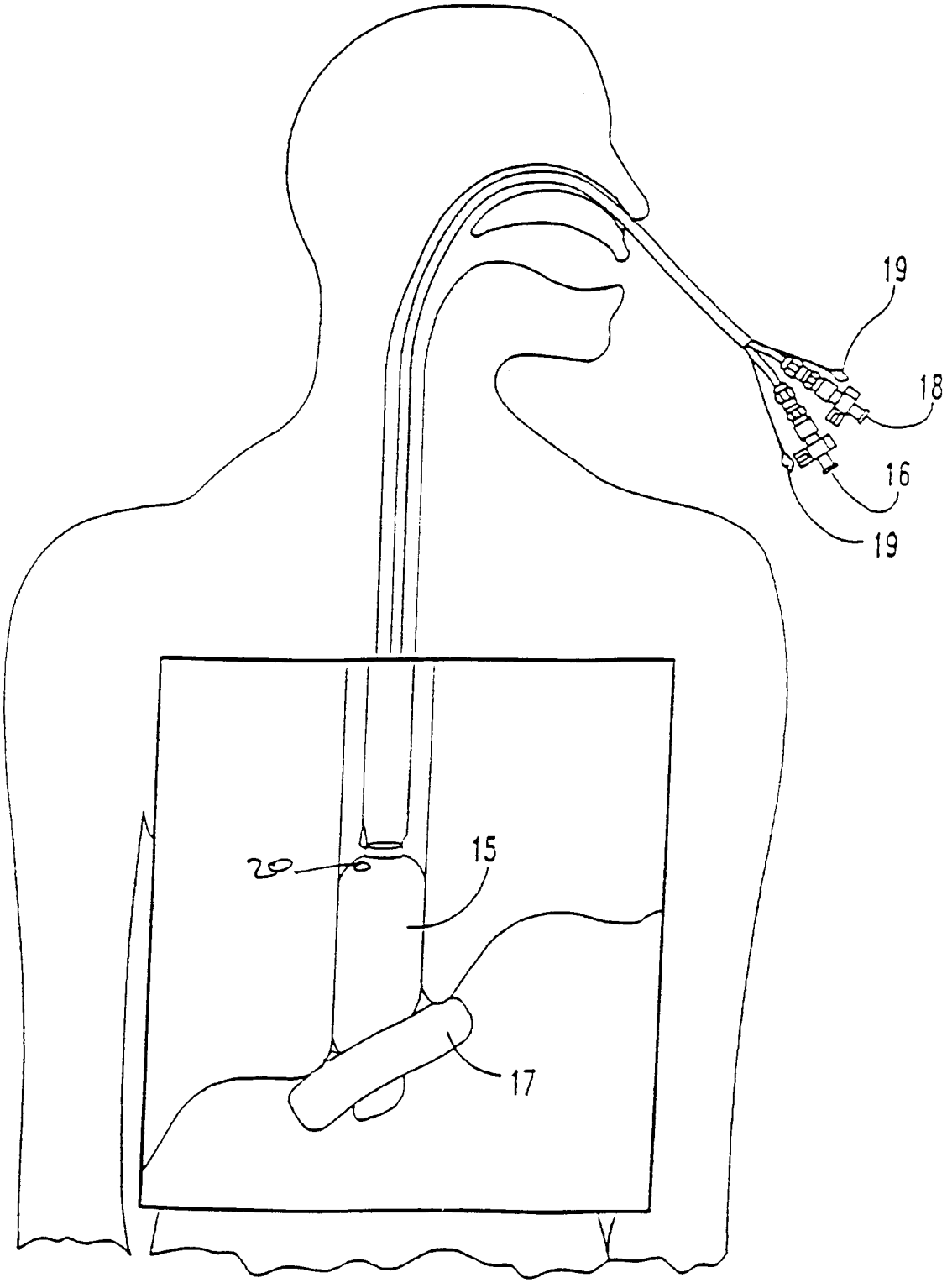

Fig. 7

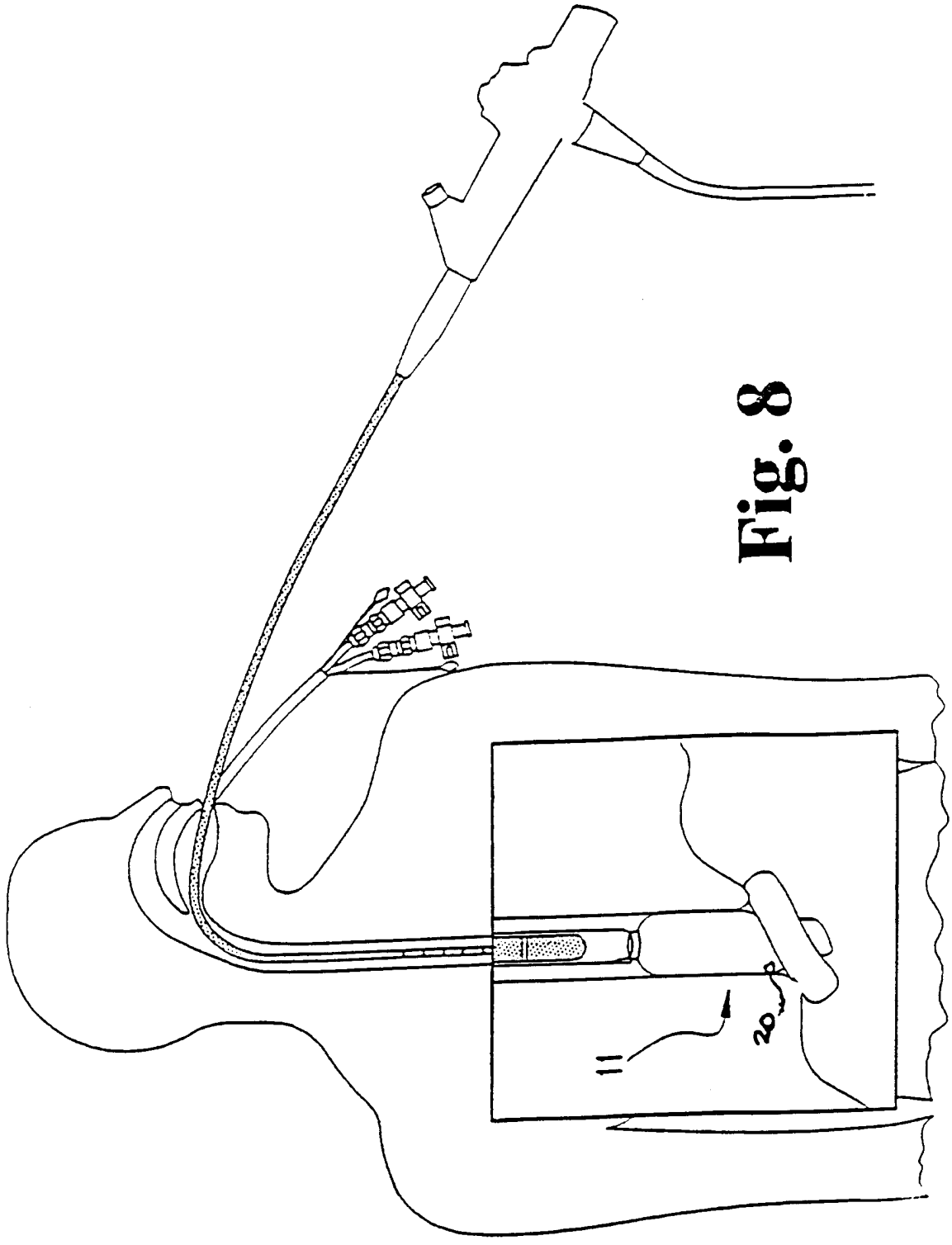

Fig. 8

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US01/00595

A. CLASSIFICATION OF SUBJECT MATTER

IPC(7) :A61B 5/02, 5/00

US CL :600/486, 485, 481, 500, 561, 593

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. : 600/481, 483-486, 488, 437, 454, 462, 466, 470, 407 500, 561, 593; 604/93, 96-98

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)

EAST

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 3,055,371 A (KULICK) 25 September 1962, col. 3, line 52 to col. 4, line 32, and see Fig. 1.	1 and 7
Y	US 5,181,517 A (HICKEY) 26 January 1993, col. 5, line 48 to col. 4, line 62 and Figs. 1-3.	1 and 7
A	US 5,398,692 A (HICKEY) 21 March 1995, col. 6, line 13 to col. 7, line 27 and Figs. 1-3.	1 and 7
Y	US 5,048,532 A (HICKEY) 17 September 1991, col. 7, line 47 to col. 8, line 24 and see Figs. 4A, 4B, and 6.	1 and 7
A	US 4,214,593 A (IMBRUCE et al) 29 July 1980, col. 3, line 23 to col. 4, line 58 and see Fig. 1.	1 and 7

[X] 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
"E"	earlier document published on or after the international filing date	"Y"	document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
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"P"	document published prior to the international filing date but later than the priority date claimed		

Date of the actual completion of the international search 02 MARCH 2001	Date of mailing of the international search report 17 APR 2001
Name and mailing address of the ISA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 Facsimile No. (703) 305-3230	Authorized officer NAVIN NATHITHADHA Telephone No. (703) 305-2445

Form PCT/ISA/210 (second sheet) (July 1998) ★

专利名称(译)	用于连续测量门静脉血压的装置和方法		
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申请号	EP2001942289	申请日	2001-01-09
[标]申请(专利权)人(译)	ZIMMON SCI		
申请(专利权)人(译)	ZIMMON科技股份有限公司		
当前申请(专利权)人(译)	ZKZ科学CORP.		
[标]发明人	ZIMMON DAVID S		
发明人	ZIMMON, DAVID, S.		
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外部链接	Espacenet		

摘要(译)

使用插入食道和胃中的填塞气球以及位于缰绳，填塞轴或食道气囊上的传感器来间歇或连续测量门静脉血压的方法和装置。安装在管上的填塞气囊横跨膈骨裂孔放置，并通过从气囊延伸到患者体外的位置的内腔逐渐膨胀。在填塞内测量的压力增加，直到横穿隔膜的侧支门静脉血流被阻断。当传感器识别出静脉曲张的直径变化，食道壁颜色的变化或血流速度的变化时，发出血流停止进入食管静脉曲张的信号。在静脉曲张血流最低点测得的填塞压力相当于门静脉血压。