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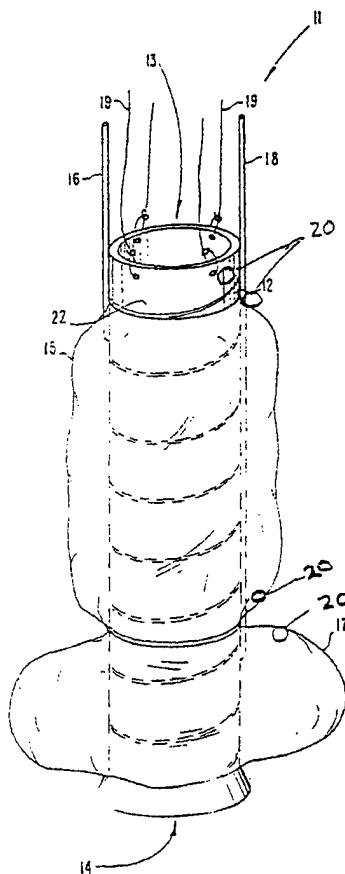
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(54) Title: **APPARATUS AND METHOD FOR CONTINUOUS MEASUREMENT OF PORTAL BLOOD PRESSURE**



(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 bridge, 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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1 APPARATUS AND METHOD FOR CONTINUOUS MEASUREMENT OF PORTAL
BLOOD PRESSURE

BACKGROUND OF THE INVENTION

6 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

1 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
6 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
11 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

16 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.

21

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

1 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
6 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
11 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
16 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
21 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

1 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
6 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
11 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
16 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
21 traction means. The bridle is manipulated to position the
proximal end of the device within the digestive tract and
maintain the device in traction.

1 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.

6 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
11 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
16 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
21 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

1 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.

6 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
11 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.

16 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
21 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

1 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.

6

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
11 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
16 periodically increases esophageal pressure to oppose
variceal pressure and influences pressure and flow in
esophageal varices.

A similar disability is present during routine
21 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-

1 visual sensor since air pressure would not be required.

6 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
11 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.

16 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,
21 that the drawings are designed as an illustration only
and not as a definition of the limits of the invention.

1 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
6 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
11 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
16 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
21 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

1 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
6 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
11 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
16 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
21 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

1 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
6 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
11 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,
16 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.

21 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

1 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
6 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.

11 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
16 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
21 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

1 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
6 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
11 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
16 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
21 while leaving a portion of the bridle external to the
patient.

1 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
6 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
11 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
16 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
21 otherwise might prevent an accurate measure of the
patient's portal blood pressure.

1 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
6 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
11 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
16 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
21 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

1 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.

6

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
11 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
16 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
21 gastric inflatable balloon is slowly reduced until the
varices distend and reappear. Pressure is then increased
in the esophageal and gastric inflatable balloon while

1 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
6 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
11 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
16 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
21 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

1 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
6 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
11 thereunto without departing from the spirit and scope of
the invention.

1 WHAT IS CLAIMED IS:

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

6 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
11 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;

16 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;

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

1 stomach;

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

6 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;

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

 releasing said traction means;

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

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

1 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
6 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
11 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
16 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
21 balloon.

5. The method of claim 4, further comprising the

1 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
6 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.

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

a tube with proximal and distal open ends,

16 an esophageal inflatable balloon mounted
over said tube;

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

a gastric inflatable balloon mounted over said

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

a sensor mounted to one of said balloons;
and

6 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
11 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
16 to extend up the esophagus to a traction means.

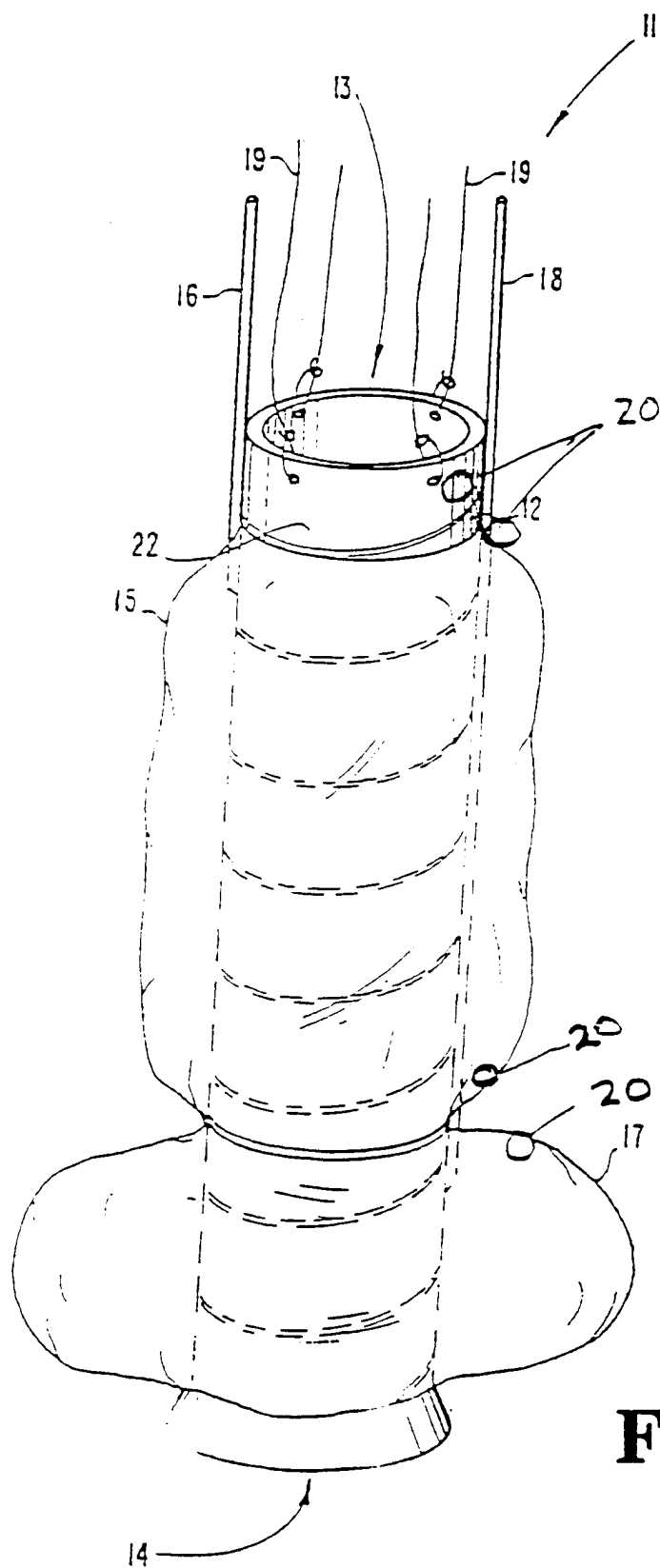
10. The device according to claim 7, further
comprising a monitor connected to said sensor for
monitoring the blood pressure sensed by said sensor.

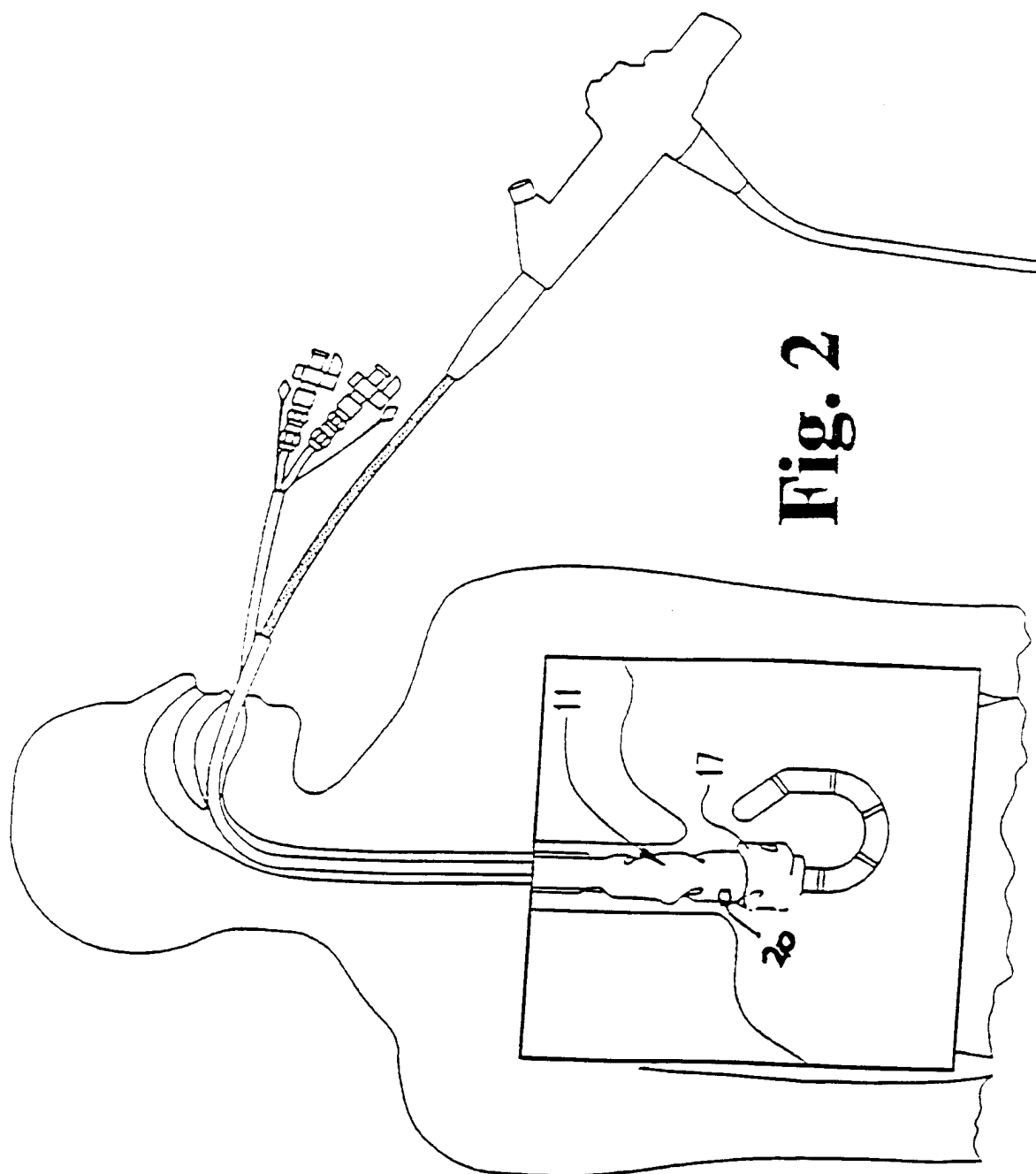
21 11. The device according to claim 9, wherein the
sensor is selected from the group consisting of an

1 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.

6

**Fig. 1**



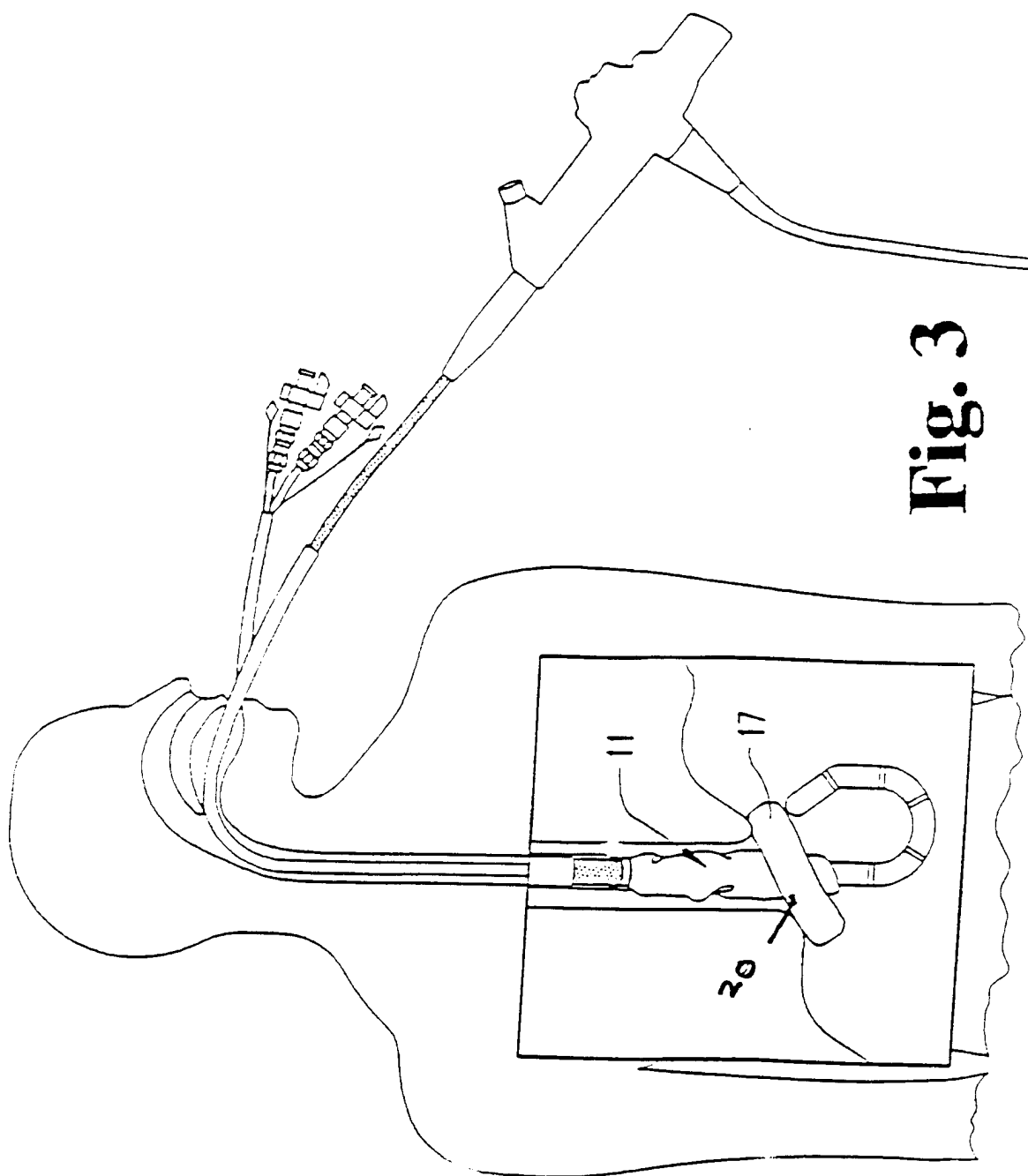


Fig. 3

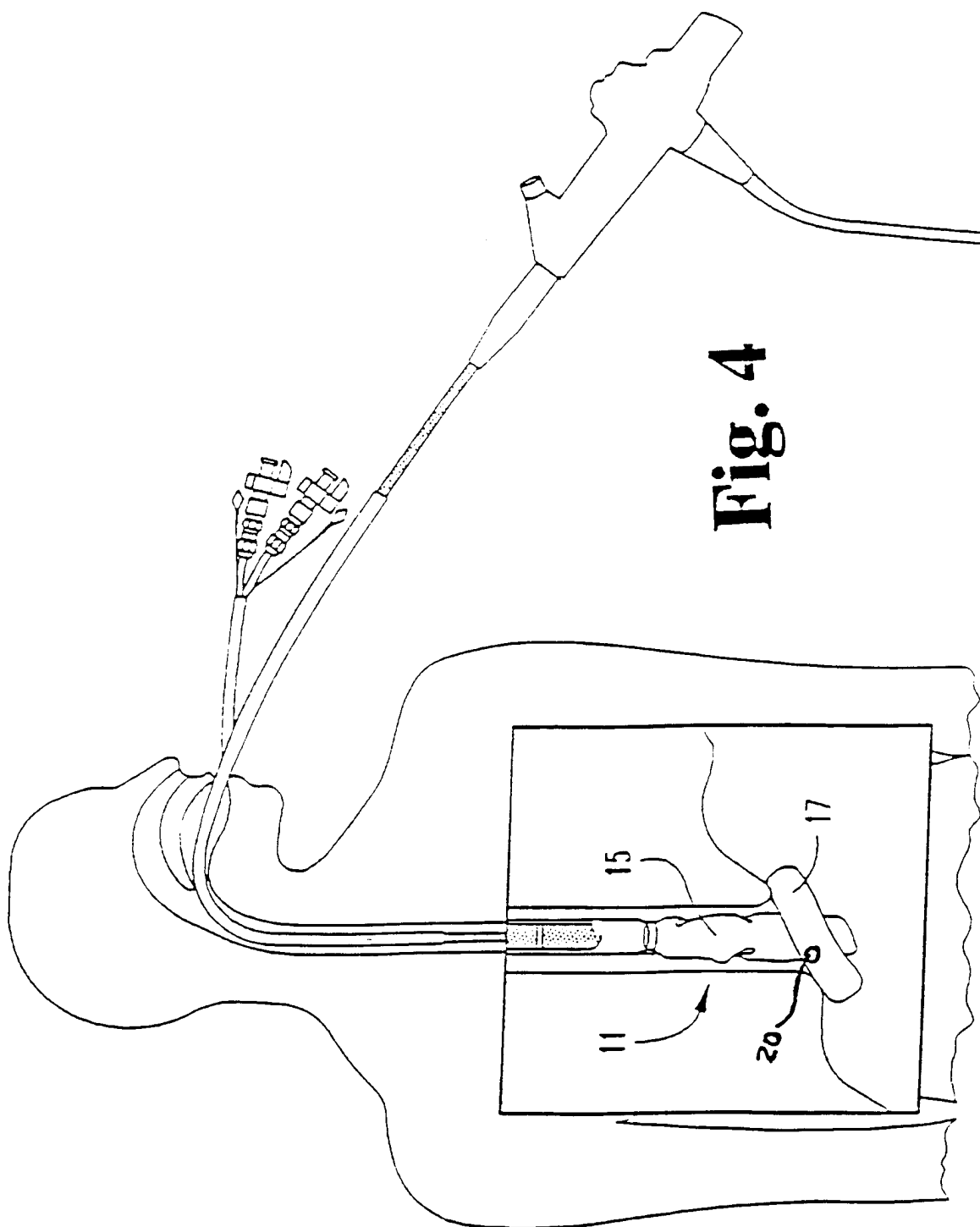


Fig. 4

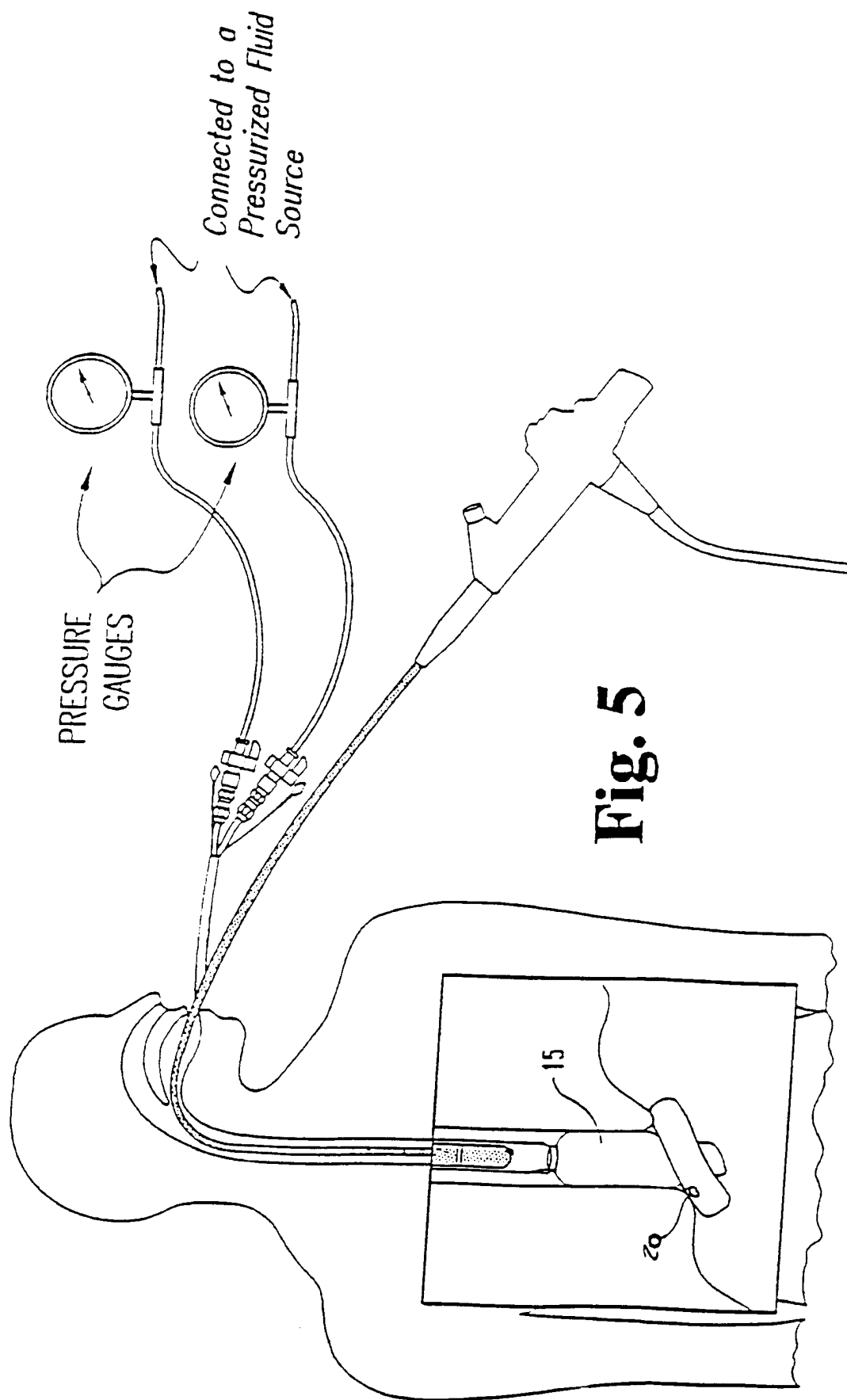


Fig. 5

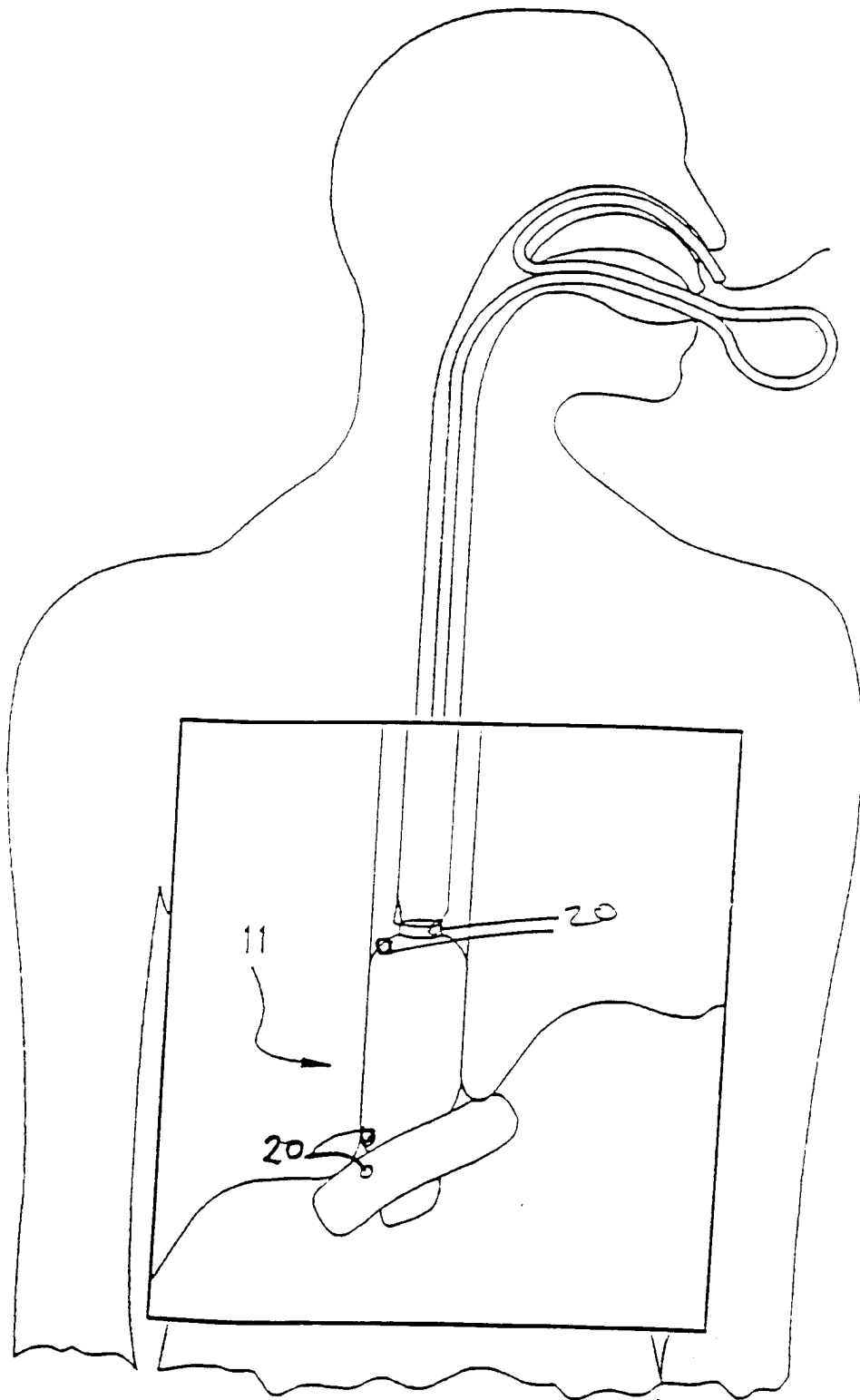
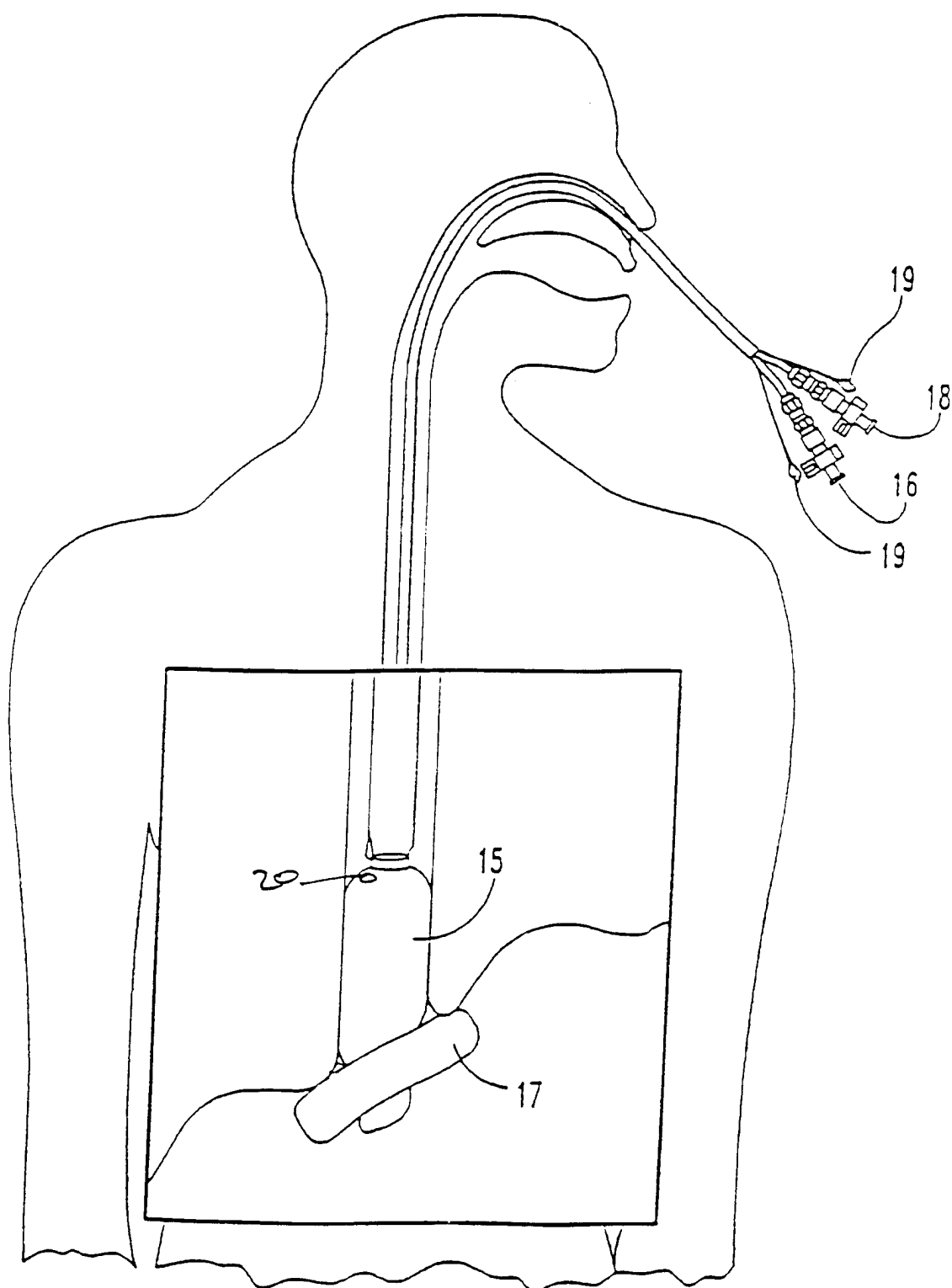


Fig. 6

**Fig. 7**

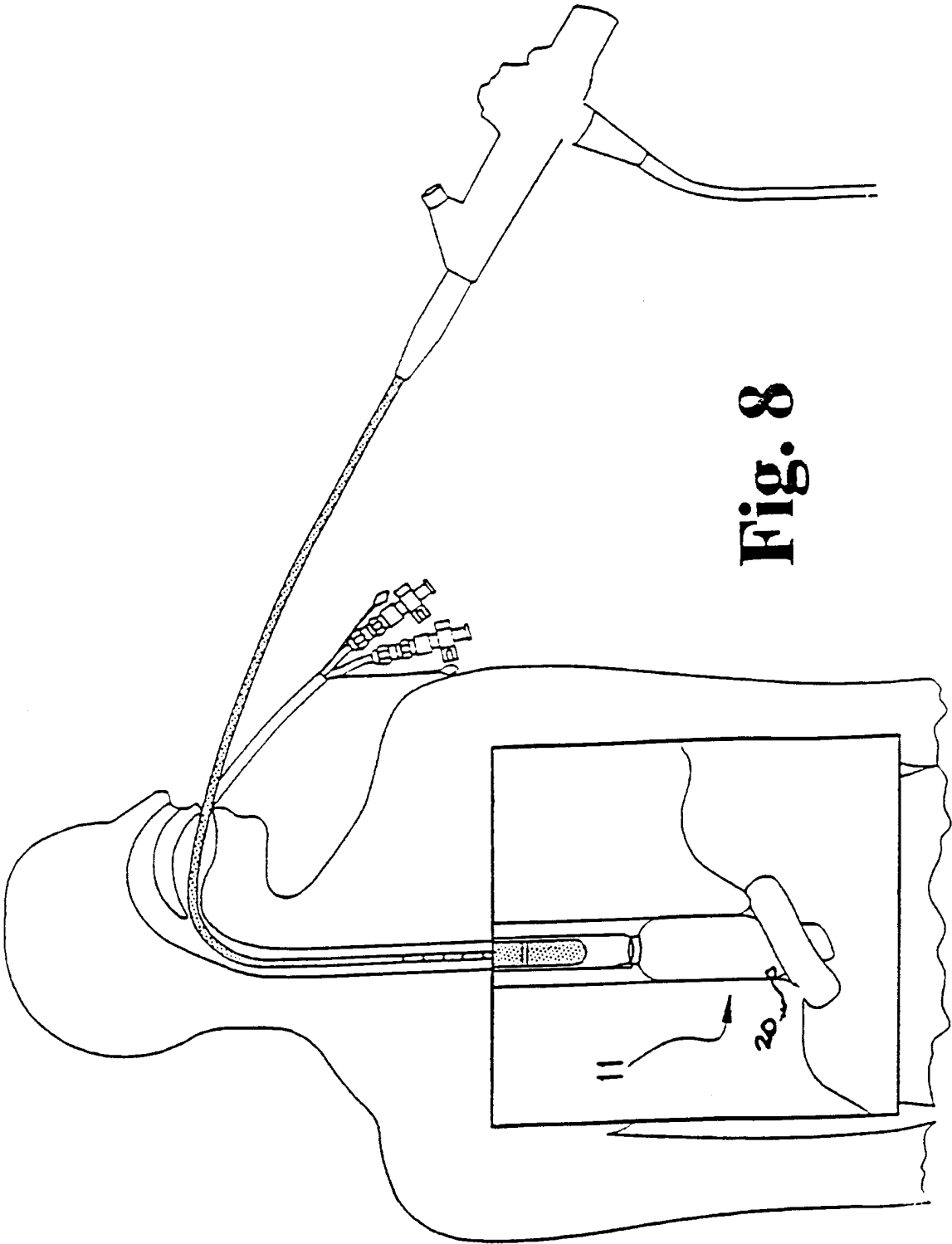
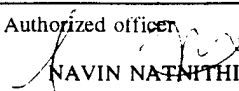


Fig. 8

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
☒ Further documents are listed in the continuation of Box C. ☐ See patent family annex.		
A	document defining the general state of the art which is not considered to be of particular relevance	*T*
E	earlier document published on or after the international filing date	*X*
L	document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	*Y*
O	document referring to an oral disclosure, use, exhibition or other means	*Z*
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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 NATNITHITHADHA Telephone No. (703) 305-2445

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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摘要(译)

使用插入食道和胃中的填塞气球以及位于缆绳，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腔逐渐膨胀。在填塞内测得的压力增加，直到横穿膈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。