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

GERÄT UND VERFAHREN ZUR KONTINUIERLICHEN MESSUNG DES PORTALEN BLUTDRUCKS

DISPOSITIF ET PROCEDE DE MESURE EN CONTINU DE PRESSION PORTALE

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Description

BACKGROUND OF THE INVENTION

1. Field of the Invention

[0001] 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

[0002] U.S. Patent No. 5,653,240 to Zimmon 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.

[0003] Patent document US-A-5,181,517 discloses also a similar apparatus for measuring portal blood pressure.

[0004] 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

[0005] It is therefore an object of the present invention, defines in the claim 1 wherein the preamble is known from US-A-5,181,517, 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.

[0006] 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.

[0007] 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.

[0008] 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.

[0009] 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.

[0010] For this purpose, deaerated fluid is gradually infused adjacent to the esophageal balloon while aspirating the stomach.

[0011] 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.

[0012] 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 al-

ternative therapy.

[0013] 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.

[0014] 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.

[0015] The preferred method for measuring portal pressure would have a tamponade balloon such as that described in United States Patent No. 5,308,326 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.

[0016] 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.

[0017] 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. 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**

[0018] 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.

[0019] 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

[0020] 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.

[0021] 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.

[0022] 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.

[0023] 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.

[0024] 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.

[0025] 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.

[0026] 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.

[0027] 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.

[0028] 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.

[0029] 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.

[0030] 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.

[0031] 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.

[0032] 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.

[0033] 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.

[0034] 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.

[0035] 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.

[0036] 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.

[0037] Further details regarding the device can be found in Method and Device for Measuring Portal Blood Pressure, U.S. Patent No. 5,653,240.

[0038] 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 scope of the invention.

Claims

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

   a tube (12) with proximal and distal open ends, an esophageal inflatable balloon (15) mounted over said tube (12);
   a first inflation lumen opening into said esophageal inflatable balloon (15) for directing pressurized fluid to inflate said esophageal inflatable balloon;
   a gastric inflatable balloon (17) mounted over said tube (12) between said esophageal inflatable balloon (15) and said distal open end;
   a sensor (20) mounted to one of said balloons for monitoring the pressure inside said balloons to obtain an indication of the portal blood pressure as the tamponade pressure required to occlude portal collateral veins;
   a second inflation lumen (18) opening into said gastric inflatable balloon (17) for directing pressurized fluid to inflate said gastric balloon; and

   characterised in that said ballons can be inflated until blood flow in the portal collateral veins traversing the diaphragmatic hiatus is occluded.

2. The device according to claim 1, further comprising a traction means (19) to seat said gastric balloon against the gastric cardia.

3. The device according to claim 1, further comprising a bridle (19) attached to the device and adapted to extend up the esophagus to a traction means.

4. The device according to claim 1, further comprising a monitor connected to said sensor (20) for monitoring the tamponade pressure and blood flow in esophageal and adjacent veins sensed by said sensor.

5. The device according to claim 3, wherein the sensor is selected from the group consisting of sensors for identifying change in diameter of the varices, change in color of the esophageal varices, change in velocity of flow.

6. The device according to claim 5, further comprising a fine tube near the bridle carrying a trickle of deaerated water or other fluid across the sensor.

Patentansprüche

1. Vorrichtung zum kontinuierlichen Messen des Pfortaderdrucks, umfassend:

   einen Schlauch (12) mit offenem proximalem und distalem Ende;
   einen aufblähbaren Ösophagusballon (15), der über dem Schlauch (12) angebracht ist;
   ein erstes Aufblählumen, das sich in den aufblähbaren Ösophagusballon (15) hinein öffnet, um ein Druckfluid zum Aufblähen des aufblähbaren Ösophagusballon zu leiten;
   einen aufblähbaren Magenballon (17), der über dem Schlauch (12) zwischen dem aufblähbaren Ösophagusballon (15) und dem offenen distalen Ende angebracht ist;
   einen Sensor (20), der an einem der Ballons angebracht ist, zum Überwachen des Drucks im Inneren der Ballons zum Erhalt einer Angabe über den Pfortaderdrucks als den zur Okklusion der Kollateralvenen der Pfortader benötigten Tamponadendruck;
   ein zweites Aufblählumen (18), das sich in den aufblähbaren Magenballon (17) hinein öffnet, um ein Druckfluid zum Aufblähen des Magenballons zu leiten;

   dadurch gekennzeichnet, dass die Ballons aufgebläht werden können, bis der Blutfluss in den Kollateralvenen der Pfortader, die den Hiatus diaphragmaticus durchqueren, okkludiert ist.

2. Vorrichtung nach Anspruch 1, ferner umfassend ein Traktionsmittel (19) zum Platzieren des Magenballons am Magenmund.

3. Vorrichtung nach Anspruch 1, ferner umfassend einen an der Vorrichtung befestigten Zügel (19), der dazu geeignet ist, sich der Speiseröhre entlang nach oben zu einem Traktionsmittel zu erstrecken.

4. Verfahren nach Anspruch 1, ferner umfassend einen mit dem Sensor (20) verbundenen Monitor zum Überwachen des vom Sensor abgefüllten Tamponadendrucks und des Blutflusses in ösophagealen und benachbarten Venen.

5. Vorrichtung nach Anspruch 3, wobei der Sensor aus der aus Sensoren zur Identifizierung einer Veränderung des Durchmessers der Varizen, einer Veränderung der Farbe der Ösophagusvarizen und einer Veränderung der Geschwindigkeit des Flusses bestehenden Gruppe ausgewählt ist.

6. Vorrichtung nach Anspruch 5, ferner umfassend einen dünnen Schlauch in der Nähe des Zügels, der ein Rinnsal entlüfteten Wassers oder eines anderen Fluids führt.

Revendications

1. Dispositif de mesure en continu de pression portale, comportant :

   un tube (12) avec des extrémités ouvertes proximale et distale,
   un ballon gonflable dans l'oesophage (15) monté sur ledit tube (12) ;
   un premier lumen d'insufflation s'ouvrant dans ledit ballon gonflable dans l'oesophage (15) pour diriger du fluide pressurisé afin de gonfler ledit ballon gonflable dans l'oesophage ;
   un ballon gonflable dans l'estomac (17) monté sur ledit tube (12) entre ledit ballon gonflable dans l'oesophage (15) et ladite extrémité ouverte distale ;
   un capteur (20) monté sur un desdits ballons pour contrôler la pression à l'intérieur desdits ballons afin d'obtenir une indication de la pression sanguine portale sous forme de pression de tamponnement requise pour occlure les veines collatérales portales ;
   un deuxième lumen d'insufflation (18) s'ouvrant dans ledit ballon gonflable dans l'estomac (17) pour diriger du fluide pressurisé afin de gonfler ledit ballon gonflable dans l'estomac ; et

   caractérisé en ce que lesdits ballons peuvent être gonflés jusqu'à ce que ce que le flux sanguin traversant le hiatus du diaphragme soit occlus.

2. Dispositif selon la revendication 1, comprenant par ailleurs un moyen de traction (19) permettant d'asseoir ledit ballon gastrique contre le cardia gastrique.

3. Dispositif selon la revendication 1, comprenant par ailleurs une bride (19) rattachée au dispositif et apte à allonger l'oesophage jusqu'à un moyen de traction.

4. Dispositif selon la revendication 1, comprenant par ailleurs un moniteur connecté audit capteur (20) pour contrôler la pression de tamponnement et le flux sanguin dans les veines de l'oesophage et adjacentes palpées par ledit capteur.

5. Dispositif selon la revendication 3, dans lequel le capteur est sélectionné parmi le groupe composé de capteurs permettant d'identifier le changement de diamètre des varices, le changement de couleur des varices d'oesophage, le changement de vitesse du flux.

6. Dispositif selon la revendication 5, comprenant par ailleurs un tube fin placé près de la bride et transportant un filet d'eau ou d'autre fluide désoxygéné dans le capteur.

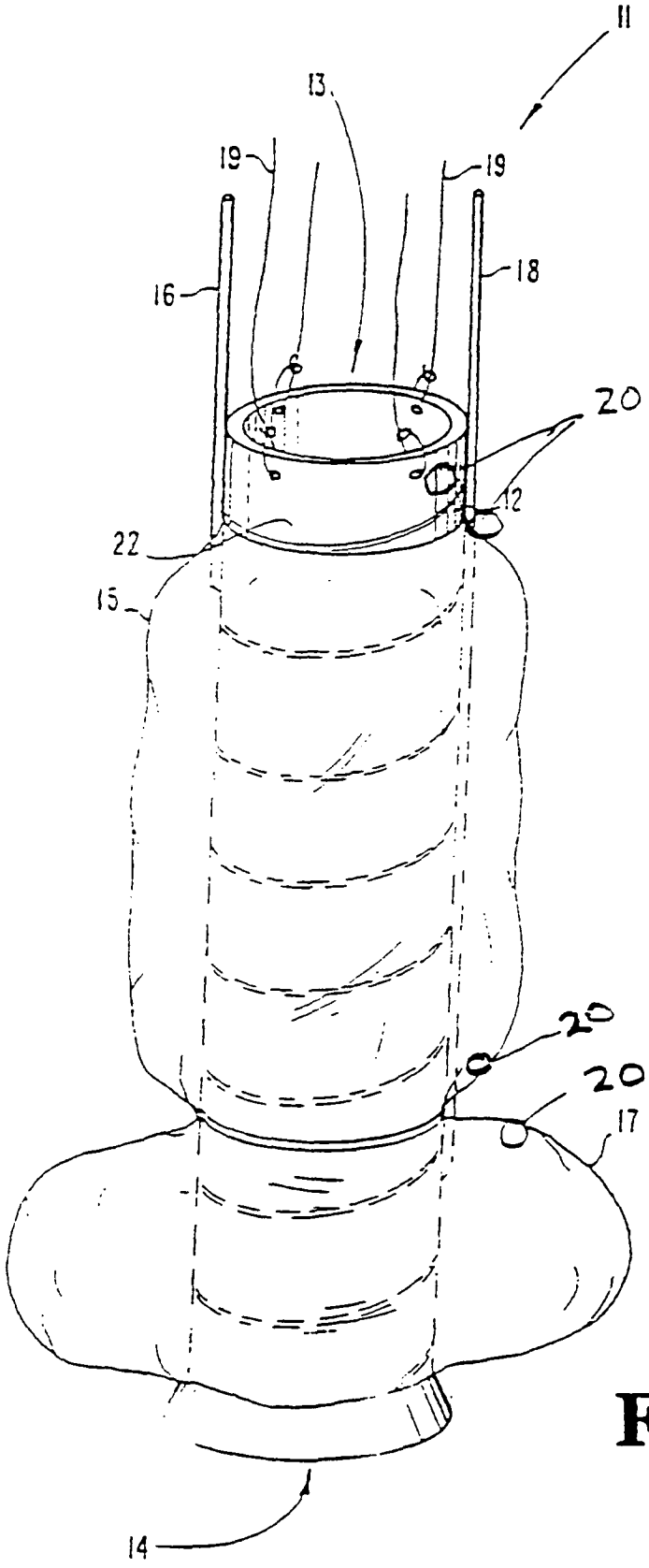

Fig. 1

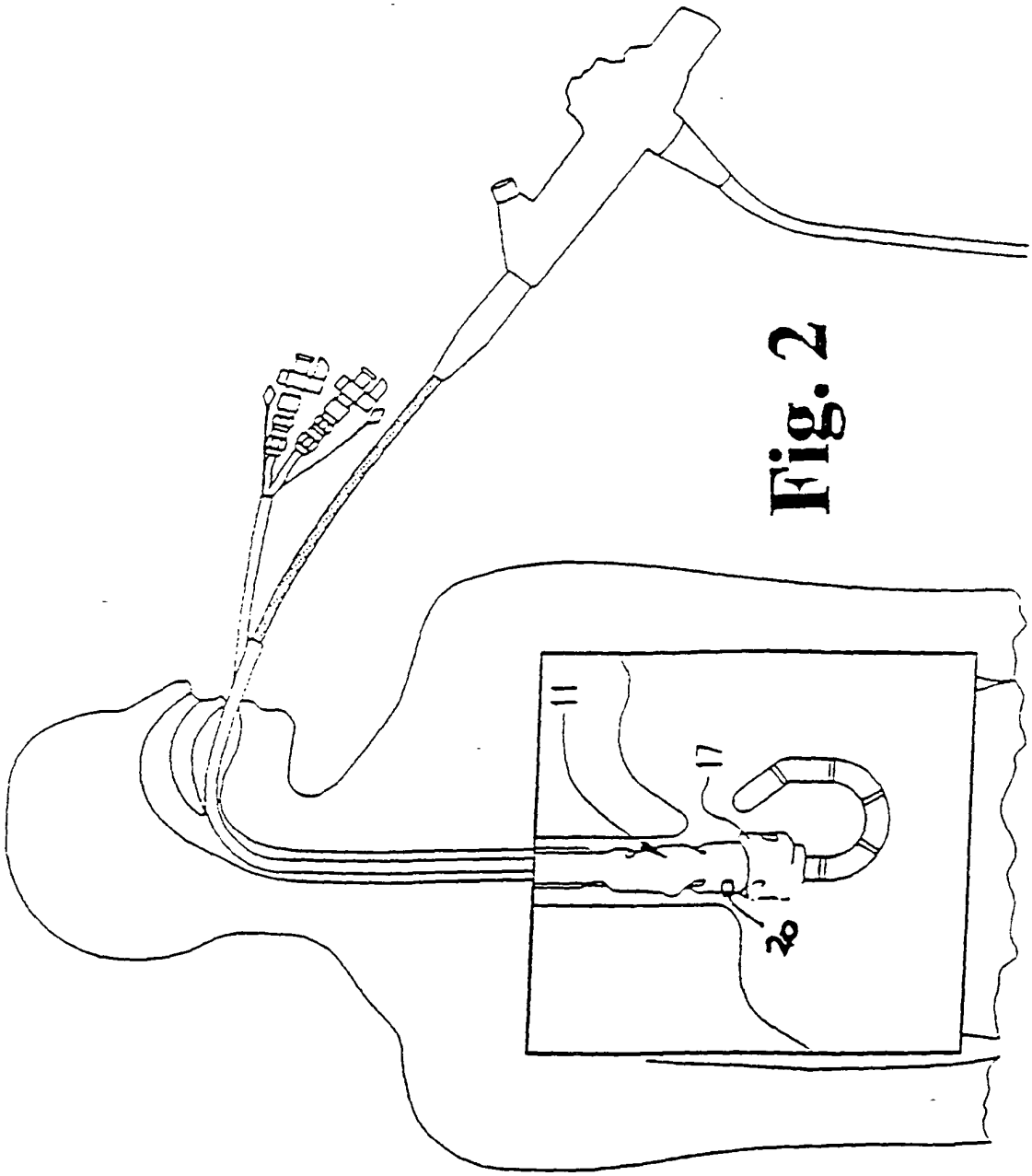

Fig. 2

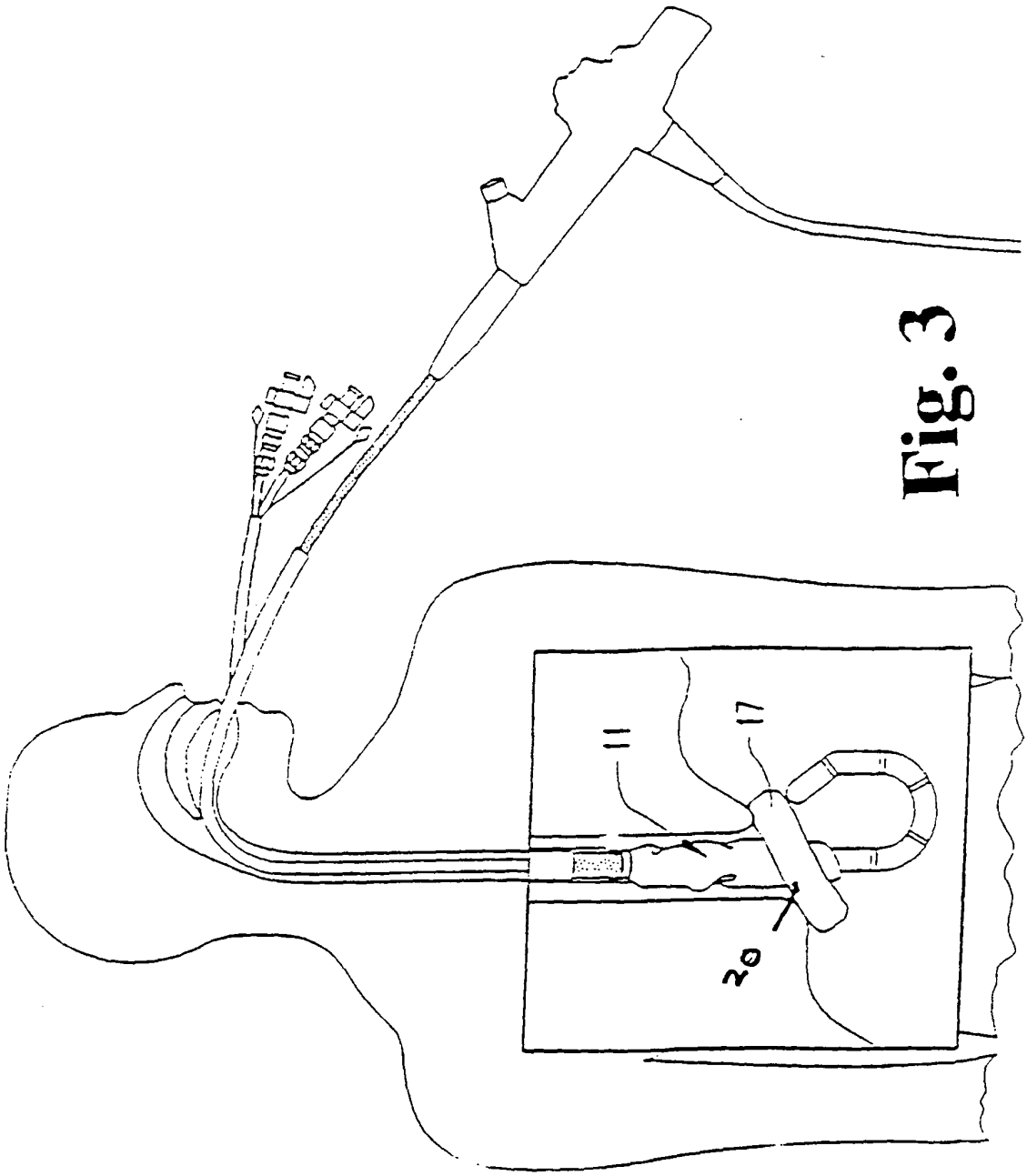

Fig. 3

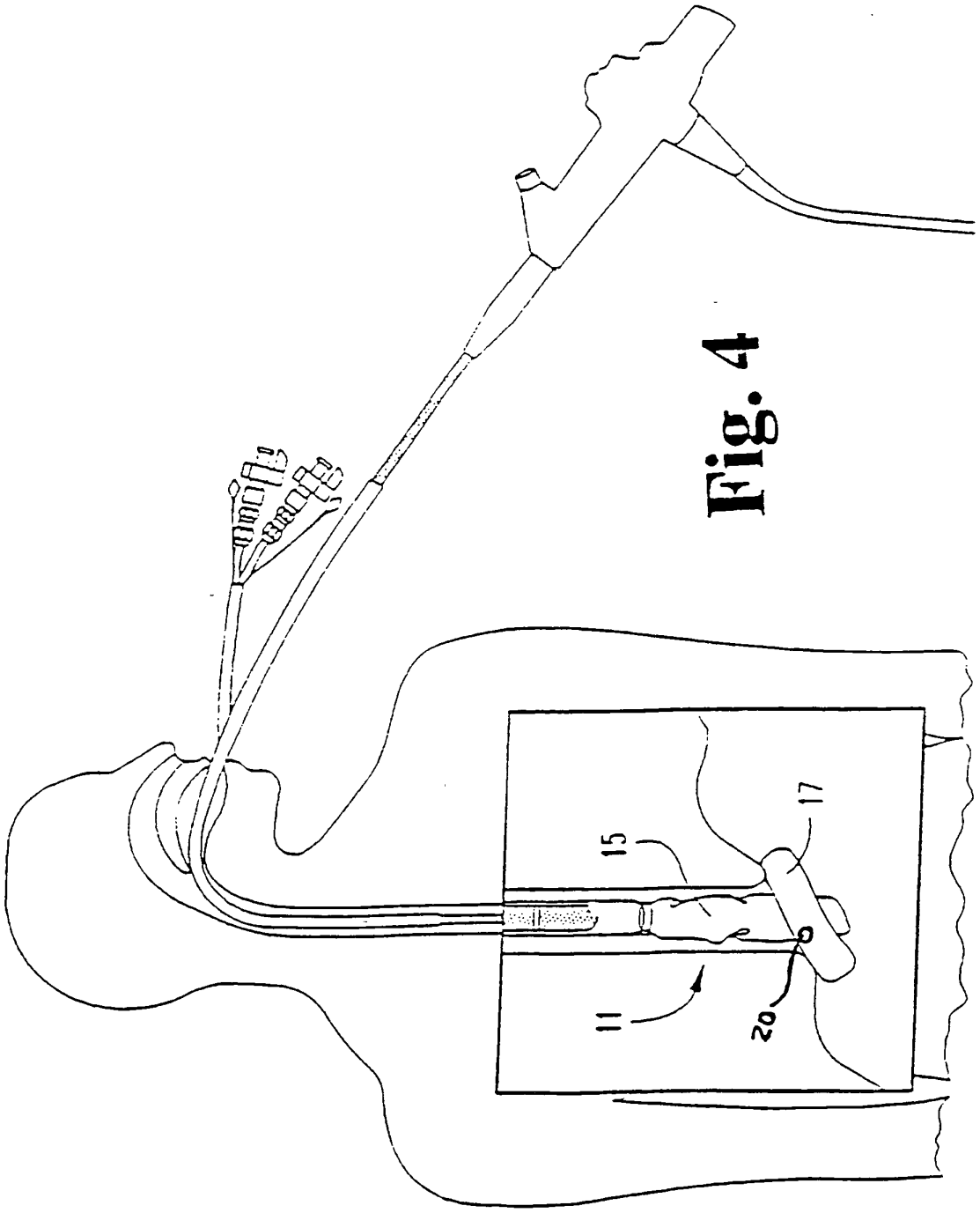

Fig. 4

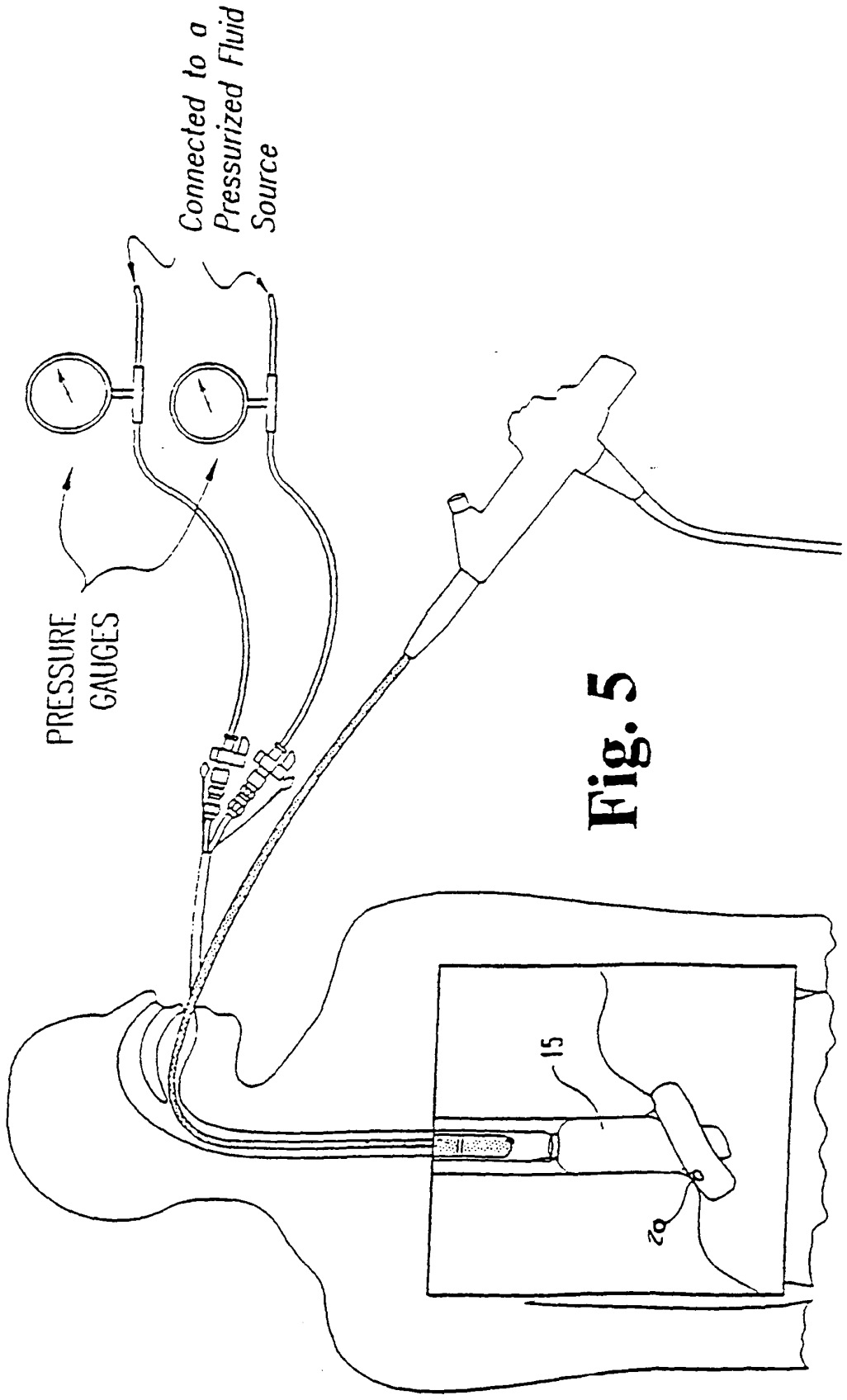
Connected to a Pressurized Fluid Source
PRESSURE GAUGES
15
20

Fig. 5

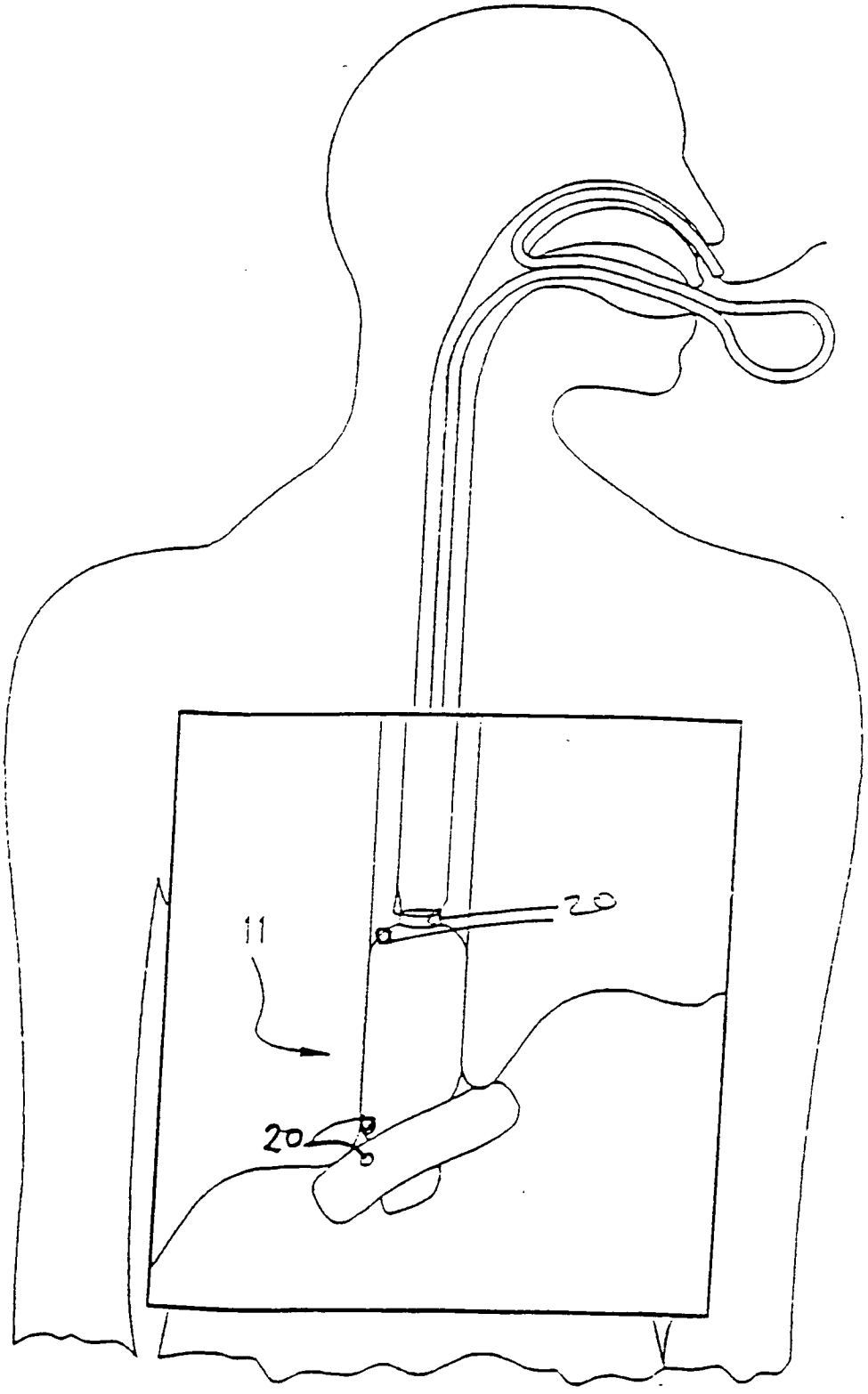

Fig. 6

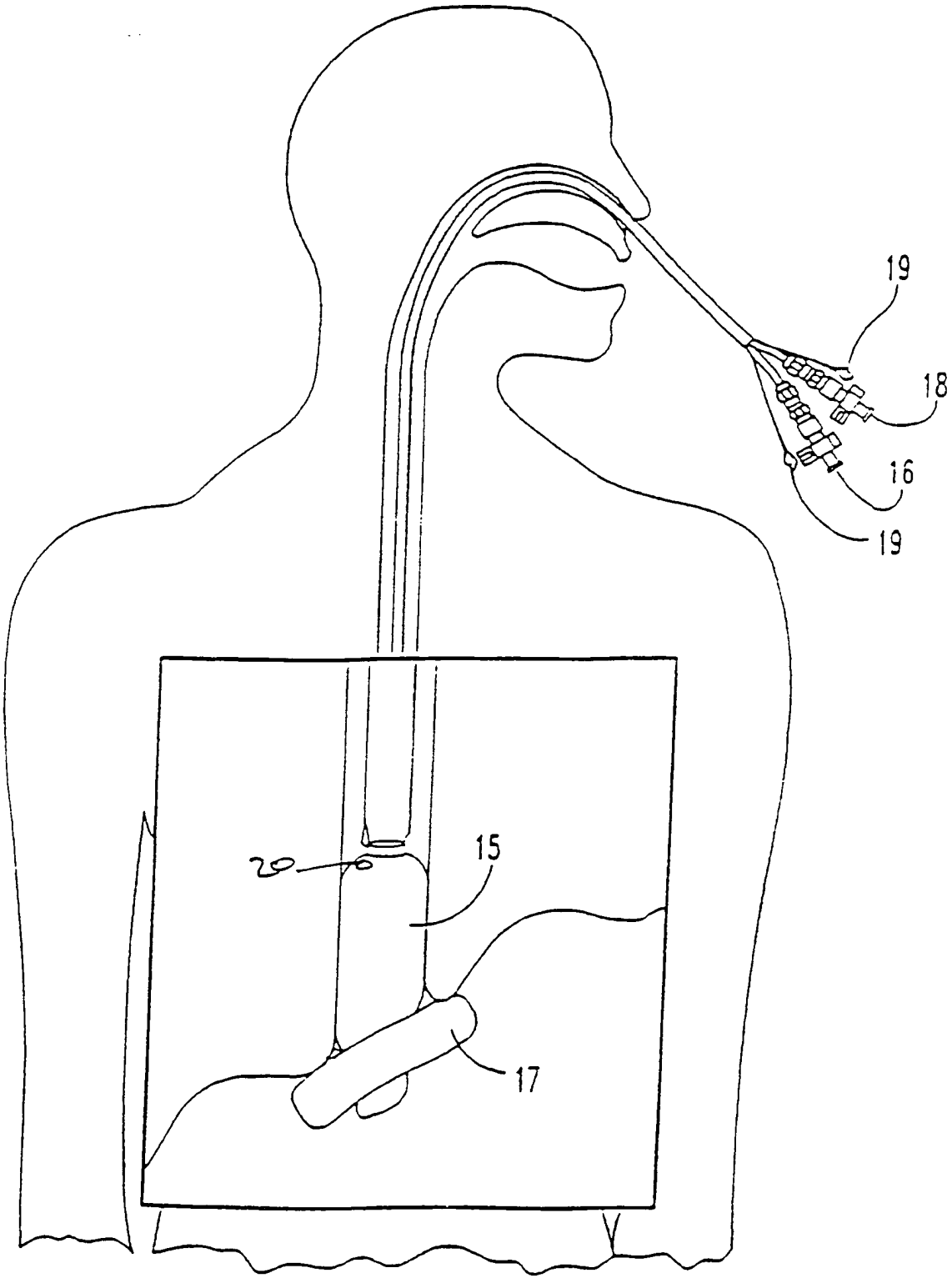

Fig. 7

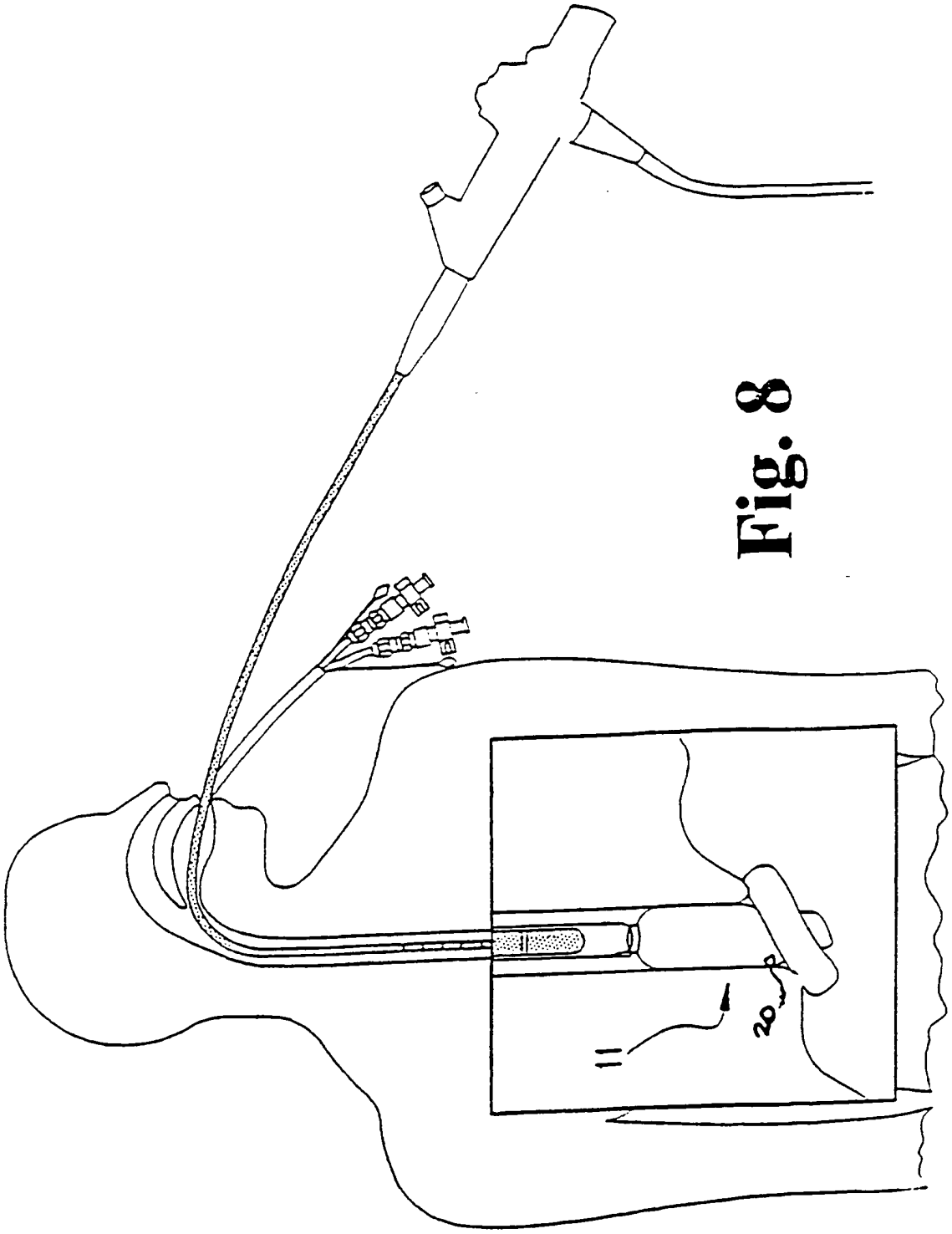

Fig. 8

REFERENCES CITED IN THE DESCRIPTION

This list of references cited by the applicant is for the reader's convenience only. It does not form part of the European patent document. Even though great care has been taken in compiling the references, errors or omissions cannot be excluded and the EPO disclaims all liability in this regard.

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- US 5653240 A, Zimmon **[0002] [0037]**
- US 5181517 A **[0003] [0005]**
- US 5308326 A **[0015] [0017]**

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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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。

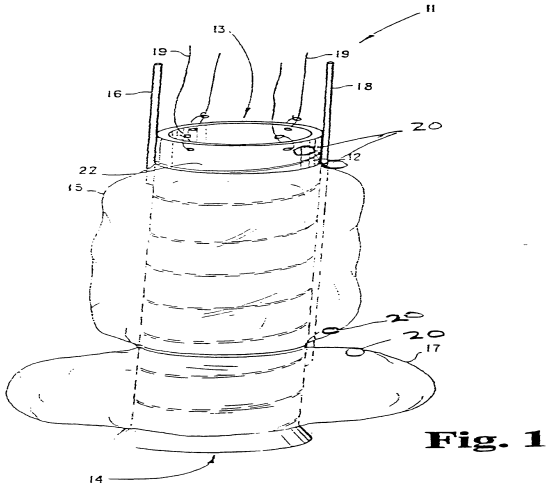

Fig. 1