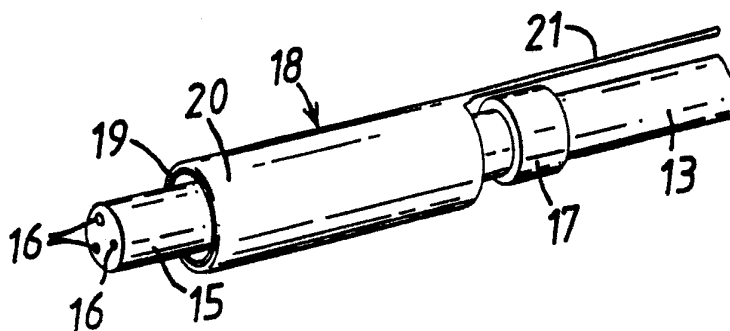




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<p>(21) International Application Number: PCT/GB87/00522 (22) International Filing Date: 21 July 1987 (21.07.87)</p> <p>(71)(72) Applicant and Inventor: TAYLOR, Thomas, Vincent [GB/GB]; 12 Stanhope Road, Bowdon, Cheshire WA14 3JY (GB).</p> <p>(74) Agent: MARSH, Roy, David; Michael Burnside & Partners, 2 Serjeants' Inn, Fleet Street, London EC4Y 1HL (GB).</p> <p>(81) Designated States: AT (European patent), AU, BE (European patent), CH (European patent), DE (European patent), DK, FI, FR (European patent), GB (European patent), IT (European patent), JP, LU (European patent), NL (European patent), NO, SE (European patent), US.</p>		<p>Published <i>With international search report.</i></p>

(54) Title: APPARATUS FOR ARREST OF BLEEDING AT A DUODENAL ULCER



(57) Abstract

Bleeding from a duodenal ulcer (12) is arrested by a tamponade technique in which a balloon (20) is introduced uninflated into the duodenum (11) on the distal end (15) of an endoscope (13). The endoscope (13) is used to position the uninflated balloon (20), the balloon (20) is inflated using an inflation line (21) and tension in the line (21) holds the balloon (20) pressed against the ulcer (12). The endoscope (13) is withdrawn and gastro-intestinal continuity is maintained through the bore of the sleeve (19) on which the balloon (20) is carried.

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APPARATUS FOR ARREST OF BLEEDING
AT A DUODENAL ULCER

There is still a high rate of mortality in patients
5 suffering from bleeding duodenal ulcers. Drug therapy
has so far proved ineffective. The usual treatment is
by blood transfusion and surgery, but surgical
mortality is relatively high. A proposal for
endoscopic laser treatment of duodenal ulcers has been
10 made, but its effectiveness has not yet been
demonstrated beyond dispute. The present invention is
aimed at mitigating these problems.

According to the present invention, there is provided
15 apparatus for arresting the bleeding of a duodenal
ulcer by the application of physical pressure to the
ulcer from within the duodenum, the apparatus
comprising an inflatable balloon, means to mount the
balloon on the distal end of an endoscope whereby the
20 balloon may be conveyed in a deflated condition to the
duodenum by the endoscope during visual inspection of
the ulcer, an inflation and traction line communicating
with the interior of the balloon and for connection
externally of the patient to a source of inflation
25 fluid and to a gripping device to maintain the line in
tension.

It is contemplated that use of the device could avoid
the need for surgery but, even if surgery is necessary,
30 proper use of the device in the period before surgery
should considerably reduce the quantity of blood which
it is necessary to transfuse into the patient, or avoid
the need for blood transfusion altogether. Surgery is

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more likely to be successful when performed on patients who have not needed large blood transfusions than on patients treated as at present, for which transfusions of many pints of blood are often essential.

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The attached drawing illustrates, by way of example, a preferred embodiment of the invention.

Figure 1 is a schematic vertical section through the stomach 10 and duodenum 11 of a patient. On the wall of the duodenum 11 is an ulcer 12. The ulcer 12 is being inspected by an endoscope 13 which extends from the mouth of the patient (not shown) through the stomach 10 and pyloric sphincter 14 to the duodenum 11. (It is normal practice to perform an endoscopic inspection on duodenal ulcers as a preliminary to surgery.) For clarity, the device according to the invention is not shown in Figure 1.

Figure 2 shows the distal end 15 of the endoscope 13, with the usual optical elements 16, which need not be described herein. Gripping the cylindrical surface of the endoscope tube 13 is a rubber band 17 which serves, in a manner described below, as a back-stop collar to the balloon of the present invention.

The balloon device 18 is in the form of a sleeve which slides over the distal end 15 of the endoscope tube 13, to be arrested and held in position at the distal end 15 by the collar 17. The sleeve 18 is made up of a relatively stiff rubber tube 19 which is flexible but, at the same time, not easily collapsible. This combination of properties is achieved by embedding

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within the tube a helical wire reinforcement coil. The tube 19 carries an annular latex or silicone rubber balloon 20. The tube 19 and collar 17 together constitute means for mounting the balloon 20 on the endoscope 13. Communicating with the interior of the balloon 20 is a tough rubber inflation and traction line 21 which is of small diameter and thin wall thickness and runs (not shown) the full length of the endoscope tube 13 so that it can be manipulated outside the mouth of the patient. The balloon 20 is shown in Figure 2 in its deflated condition, and with exaggerated transverse dimensions. In practice, the balloon device 18 and collar 17 add little to the cross sectional area of the endoscope, so that penetration through the sphincter 14 is not a problem.

In use of the device, the collar 17, and then the balloon device 18, is slid onto the distal end 15 of the tube 13. The endoscope is then introduced into the duodenum, in conventional manner, with the inflation and traction line 21 available for manipulation at the mouth of the patient. The ulcer 12 is inspected, in the conventional way.

At this point, the endoscope tube 13 is manipulated further, in order to bring the balloon device 18 into what is considered to be the optimum position for inflation, for the application of physical pressure to the ulcer 12. When the balloon is in the desired position, inflation fluid is delivered to it along the inflation line 21 and, when the balloon 18 is inflated, the endoscope is withdrawn. The inflation and traction line 21 is gripped at or close to the mouth of the

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Patient, so that it is in sufficient tension to prevent the balloon 18 from moving downwardly away from the site of the ulcer 12.

One convenient way of doing this is shown in Figure 3. A hollow sphere 30 of resilient material about 7cm in diameter has a diametral slit 31 extending half way across the sphere. The sphere is of thin, tough and resilient rubber, so it grips the inflation line securely in the slit and seals the line. The sphere as a whole is, however, soft and deformable enough to lie pressed to the mouth of the patient with the ball surface against the patient's cheek, to keep the inflation line in tension.

Upward movement of the balloon is prevented by the action of the sphincter 14. Gastro-intestinal continuity is provided through the cylindrical bore at the centre of the balloon device 18, where the endoscope tube 13 was previously.

The pressure which the balloon 18 applies to the ulcer 12 may be sufficient to arrest bleeding and avoid the need for surgery. Even if surgery is necessary, the pressure on the ulcer in the period prior to surgery will arrest or substantially reduce bleeding during this period, so that the patient is kept in better condition to survive surgery.

For removal of the balloon device 18, the inflation gas is allowed to exit along the line 21, so that the balloon may deflate fully and be drawn upwardly through the sphincter 14 and stomach 10.

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Other embodiments are contemplated. In particular, the cylindrical bore which maintains gastrointestinal continuity may not be absolutely essential but it is desirable since obstruction of the duodenum is likely to produce hyper-secretion.

The technique of applying physical pressure to stop bleeding may be considered as a tamponade. The inflation and traction line is likely to have a length of around 70 to 80 cms. Because of their relatively small cross-sectional dimension, paediatric endoscopes may find special application for use with the present invention.

The fluid used for inflation may be liquid or gas. Liquid affords easier measurement of the size of the inflated balloon, because it is incompressible. Gas, however, has the advantage that the fluid pressure within the balloon is more easily monitored.

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Claims:

1. Apparatus for arresting the bleeding of a duodenal ulcer (12) by the application of physical pressure to the ulcer from within the duodenum, the apparatus comprising an inflatable balloon (20), means (17,19) to mount the balloon on the distal end (15) of an endoscope (13) whereby the balloon may be conveyed in a deflated condition to the duodenum by the endoscope during visual inspection of the ulcer, and an inflation and traction line (21) communicating with the interior of the balloon and for connection externally of the patient to a source of inflation fluid and to a gripping device (30,31) to maintain the line in tension.
2. Apparatus as claimed in claim 1 wherein the mounting means comprises a back-stop collar (17) for fitting to the outside surface of the distal end (15) of the endoscope (13), and a sleeve (19) which carries the balloon (20) and slides over the said outside surface until its sliding movement is arrested by contact with the collar.
3. Apparatus as claimed in claim 2 wherein the collar is a rubber band.
4. Apparatus as claimed in claim 2 or 3 wherein the sleeve comprises a flexible rubber tube
5. Apparatus as claimed in claim 4 wherein the rubber tube has embedded within it a helical wire reinforcement coil which prevents collapse of the tube.

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6. Apparatus as claimed in any one of the preceding claims wherein the balloon (20) is annular, having a bore (19) into which the distal end (15) of the endoscope extends and which allows gastrointestinal continuity after withdrawal of the endoscope.

7. Apparatus as claimed in any one of the preceding claims wherein the inflation and traction line (12) has a length of from 70 to 80 cms.

8. Apparatus as claimed in any one of the preceding claims with dimensions which permit it to be mounted on a paediatric endoscope (13).

9. A method of arresting the bleeding of a duodenal ulcer comprising the steps of:

a) providing on the distal end of an endoscope a deflated balloon having an inflation and traction line;

b) using the endoscope, positioning the balloon in the duodenum and inflating it using the inflation line;

c) placing the inflation line in traction to cause the balloon to apply physical pressure to the ulcer; and

(d) gripping the inflation and traction line at the mouth of the patient to maintain the line in tension.

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FIG.1

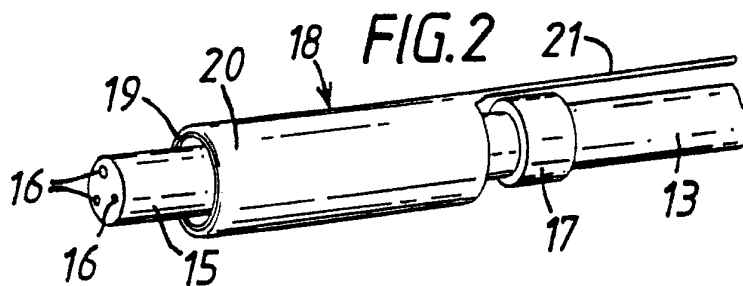
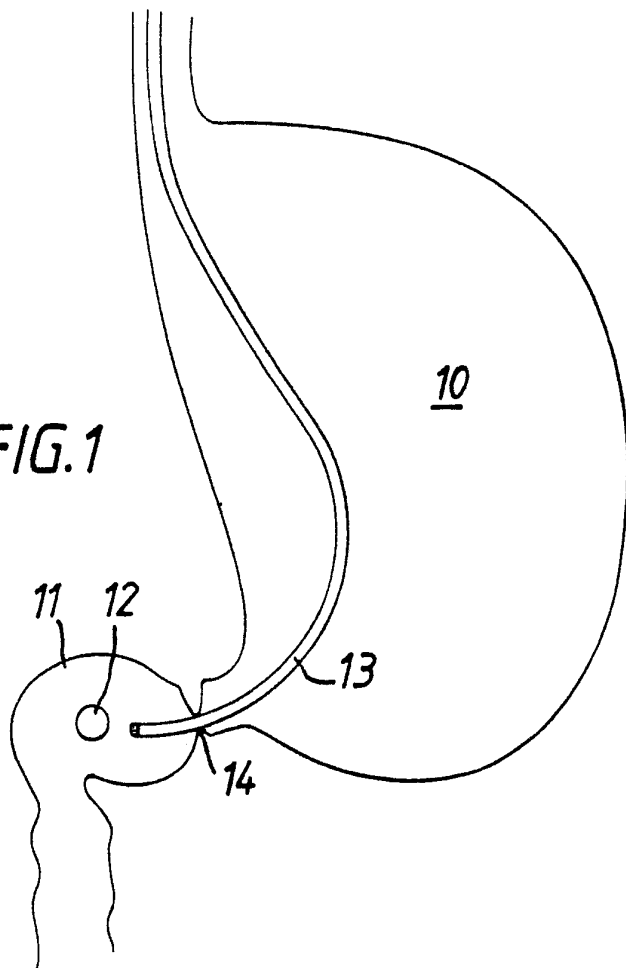
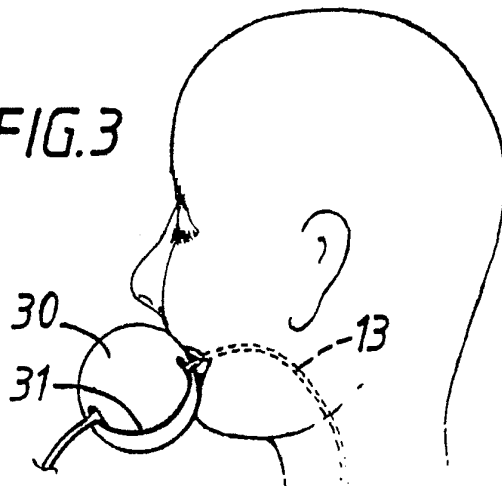


FIG.3




INTERNATIONAL SEARCH REPORT

International Application No

PCT/GB 87/00522

I. CLASSIFICATION OF SUBJECT MATTER (if several classification symbols apply indicate all: ⁶)		
According to International Patent Classification (IPC) or to both National Classification and IPC		
IPC ⁴ : A 61 B 17/12; A 61 B 1/12; A 61 M 29/02		
II. FIELDS SEARCHED		
Minimum Documentation Searched ⁷		
Classification System ¹	Classification Symbols	
IPC ⁴	A 61 B; A 61 M	
Documentation Searched other than Minimum Documentation to the Extent that such Documents are Included in the Fields Searched ⁸		
III. DOCUMENTS CONSIDERED TO BE RELEVANT ⁹		
Category ⁹	Citation of Document, ¹¹ with indication, where appropriate, of the relevant passages ¹²	Relevant to Claim No. ¹³
Y	WO, A, 86/03129 (BONZEL) 5 June 1986 see figures 1-3; page 2, lines 11-29; page 3, lines 25-27; page 4, lines 1-12, 25-27; page 7, lines 5-9	1,3,4,6, 8
A	--	2,5,7
Y	US, A, 4367747 (WITZEL) 11 January 1983 see figures; column 3, line 63 - column 4, line 4; column 4, lines 8-11, 18-20	1,3,4,6, 8
E	--	1-8
A	GB, A, 2185400 (TAYLOR) 22 July 1987 see the whole document	1
A	Surgery, volume 1, no. 24, September 1985, Medical Education (International) Ltd, (Oxford, GB), T.T. McCormack: "Balloon tamponade for bleeding oesophageal varices", pages 571a,571b	1

<p>¹⁰ * Special categories of cited documents:</p> <p>"A" document defining the general state of the art which is not considered to be of particular relevance</p> <p>"E" earlier document but published on or after the international filing date</p> <p>"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)</p> <p>"O" document referring to an oral disclosure, use, exhibition or other means</p> <p>"P" document published prior to the international filing date but later than the priority date claimed</p> <p>"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</p> <p>"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step</p> <p>"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.</p> <p>"A" document member of the same patent family</p>		
IV. CERTIFICATION		
Date of the Actual Completion of the International Search	Date of Mailing of this International Search Report	
18th March 1988	15 ADD 1988	
International Searching Authority	Signature of Authorized Officer	
EUROPEAN PATENT OFFICE	 P.C.G. VAN DER PUTTEN	

**ANNEX TO THE INTERNATIONAL SEARCH REPORT
ON INTERNATIONAL PATENT APPLICATION NO.**

GE 8700520
SA 18030

This annex lists the patent family members relating to the patent documents cited in the above-mentioned international search report. The members are as contained in the European Patent Office EDP file on 06/04/83. The European Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO-A- 8603129	05-06-86	DE-A, C 3442736 EP-A- 0203945	05-06-86 10-12-86
US-A- 4367747	11-01-83	None	
GB-A- 2185400	22-07-87	None	

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