Nov. 19, 1968 R. C. WINGROVE 3,411,507

METHOD OF GASTROINTESTINAL STIMULATION WITH ELECTRICAL PULSES

Filed April 1, 1964 2 Sheets-Sheet 1

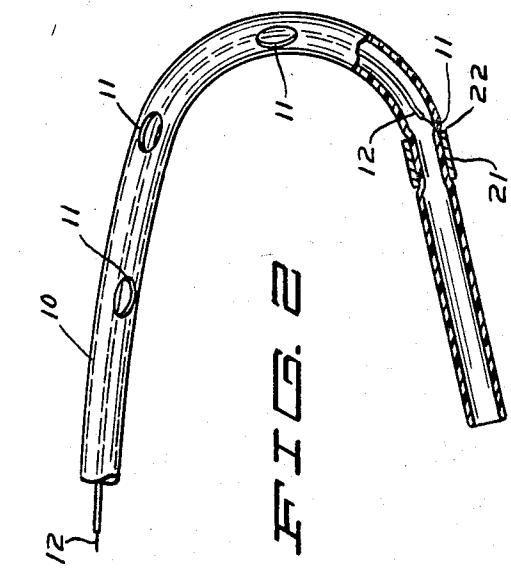

FIG. 2

FIG. 1

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FIG. 4

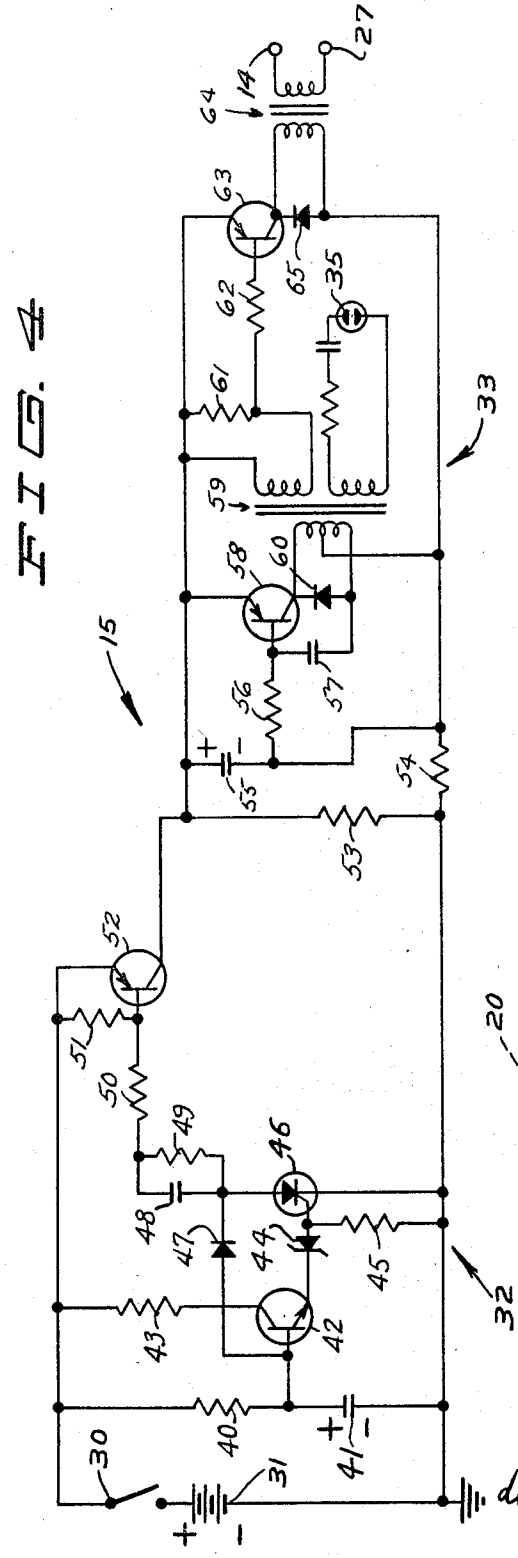
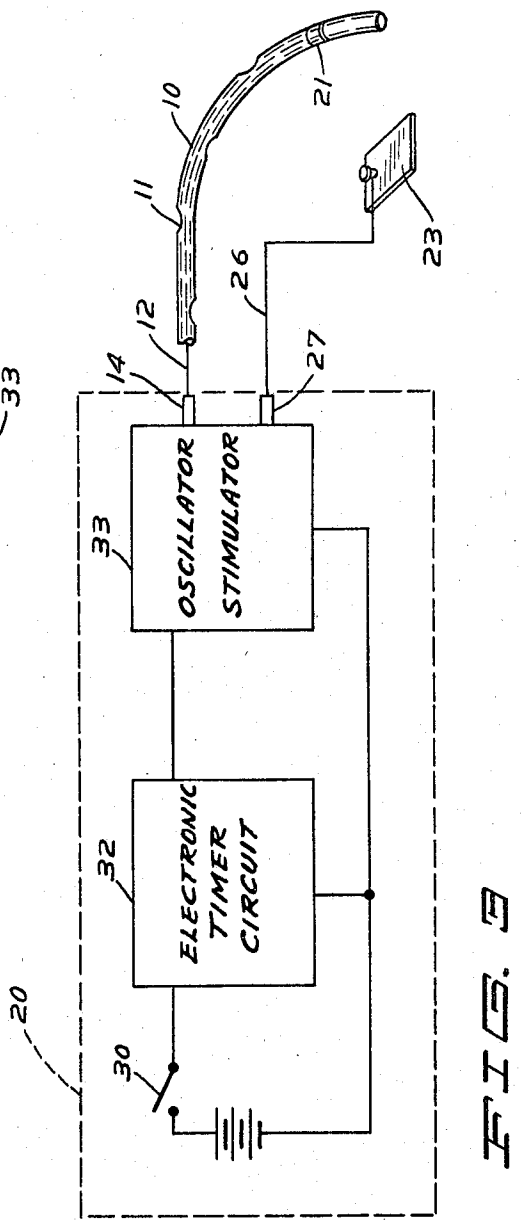


FIG. 5



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METHOD OF GASTROINTESTINAL STIMULATION WITH ELECTRICAL PULSES

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This invention has relation to a method for electrical pacing of the intestines as an effective means in the management of so-called paralytic ileus. The method of the present invention involves introducing a specific electrode nasogastrically into the stomach in proximity to or past the pyloric valve. An indifferent plate electrode is applied to the body of the patient at a convenient location such as the abdominal wall, and electrical impulses of predetermined duration and magnitude are applied between the electrodes. This causes peristaltic waves to be induced in the antrum; and these waves cross the pylorus and are carried down to the duodenum. Here these waves necessarily activate the duodenum which in turn, having a pacemaker area of its own, is thus stimulated and may control the rest of the intestinal tract. The observed result is that peristaltic activity is rapidly restored; passage of feces or flatus generally occurring four to sixteen hours after the electrical stimulation has been initiated.

Before the development of the method of the invention, a catheter was introduced into the stomach in proximity to or past the pylorus in order to perform normal post-operative gastic suction. When the method of the invention is used, this suction will generally be unnecessary and quite often oral administrations of fluids may begin immediately, thereby eliminating or at least substantially reducing the need for intravenous replacement of fluids and electrolytes normally lost by such suction. As gastrointestinal mobility can be induced and maintained by use of the invention and the swallowed gas or gas formed in the intestines are thus carried away by peristalsis, the need for the suction or delivery aspects of the cathether are greatly lessened.

However, a combination of nasogastric suction and electrical stimulation in accordance with the invention is sometimes desirable at the start of therapy in cases with a full-blown picture of ileus. For this reason, the electrode for stimulation at or near the pylorus is situated at or near the tip of an ordinary plastic nasogastric tube, and the electrical lead to that electrode extends out through the tube to position where the electrical stimulation is applied to it.

The problem

Paralytic ileus is a form of intestinal obstruction characterized by inadequate peristaltic activity affecting the gastrointestinal system in its entirety or segmantally. Loss of normal peristaltic activity frequently occurs following intra-abdominal surgery, and secondary to a variety of pathological conditions such as peritonitis of various etiologies, retroperitoneal sepsis and hemorrhage, and from trauma, infections, or surgery in areas remote from the abdominal cavity. Spinal injuries, diseases of the genito-urinary tract, and thoracic surgery or trauma are frequently observed causes of paresis of the bowel occurring as a reflex inhibition. Loss of effective peristaltic activity of the gastrointestinal tract rapidly leads to distention of bowel loops with fluid and gas which, if left untreated, is prone to perpetuate itself as a vicious cycle, the more distention occurring the more paralyzed the bowel becomes. Fluid and electrolytes are lost into this third space and distention of the intestine further impairs obsorption. In addition, distended inactive loops may twist or kink and a mechanical obstruction thus may be superimposed.

Management of this condition heretofore has been

largely passive in nature and has not changed significantly since introduction of nasogastric intubation and suction with administration of intravenous fluids and electrolytes continued until the paretic bowel resumes its tonus and peristaltic activity. Hypertonic saline, multiple enemas, spinal anesthesia, repeated use of hot stupes to the abdomen, and bowel stimulants such as prostigimine, nestigmine, pitressin, and pantothenic acid have all been used with variable and inconsistent success.

Use of the method of the invention has been found effective to induce and maintain gastrointestinal activity when such paralytic ileus occurs. This early return of bowel activity has reduced the time interval required for intravenous administration of fluid and electrolytes and the period during which a catheter must be used has been shortened or eliminated except as the catheter is used as a means for placing the specific electrode of the invention. Oral intake by the patient is resumed sooner.

In the drawings,

FIG. 1 is an elevational view of the apparatus of the invention and a diagrammatic representation of its location when in use on a patient suffering from so-called paralytic ileus;

FIG. 2 is a fragmentary elevational view of the terminal end of a nasogastric catheter with parts in section and parts broken away showing the installation of a specific electrode of the invention and its electrical lead wire on the catheter;

FIG. 3 is a block diagram of one form of electrical circuitry for energizing the electrodes of the apparatus of the invention; and

FIG. 4 is a circuit diagram of one form of circuit useful in supplying the electrical energy to perform the method of the invention.

Referring now to the drawing and the numerals of reference thereon, a nasogastric catheter **10** is provided with the usual openings **11** which are useful in its normal use as a catheter. An electrical lead wire **12** extends through the catheter for a substantial portion of its length, leaving the catheter as at **13** to extend to a first terminal **14** of an electrical stimulator circuit indicated generally in FIG. 4 as **15**, said circuit being encased in stimulator case **20**.

The terminal end of the electrical lead wire **12** is soldered or fastened in some other suitable way to a cylindrical shaped specific electrode **21** as at **22**, said wire extending through one of the openings **11** in the catheter **10**.

As is clearly seen in FIG. 1, a nosagastric tube or catheter **10** is passed into the stomach transnasally and advanced to lie in the antral region. An indifferent electrode **23** is secured to the abdominal wall by means of surgical tape **24**. In order to secure good electrical contact, it is advisable to use a small amount of electrode paste between the electrode **23** and the abdominal wall. An electrical lead wire **26** extends from this electrode **23** to a second terminal **27** of the electrical stimulator circuit **15**.

If operative incisions, or dressings, or other obstructions do not permit the positioning of the indifferent electrode **23** as shown and described, this electrode may be applied to the flanks or to the dorsal abdominal wall.

With the apparatus in position as shown and described, an "On-Off" switch **30** will be turned on thus connecting a battery **31** to the timer circuit **32** and oscillator circuit **33**. The area immediately adjacent the specific electrode **21** will then be stimulated as the electrical current passes from this specific electrode to the indifferent electrode. A discharge device or bulb **35** provides a visual indication of current flow and duration.

Operation of FIG. 4 is as follows. Closing switch **30** causes current to flow in the first timing network including resistor **40** and capacitor **41**. Accumulation of charge

on capacitor **41** forward biases the emitter-base junction of emitter follower transistor **42**. However, no current flows through the collector-emitter circuit of transistor **42**, current limiting resistor **43**, Zener diode **44**, and resistor **45** until the voltage rating, normally about four volts, of Zener diode **44** has been overcome. The values of timing resistor **40** and capacitor **41** are chosen so that it takes about fifty seconds after closing switch **30** to reach a voltage sufficient to cause flow in the collector-emitter circuit of transistor **42**.

As soon as current flows through Zener diode **4**, firing voltage is applied to the gate of SCR **46**. As soon as SCR **46** fires, capacitor **41** discharges through diode **47** and conducting SCR **46**. Dumping of capacitor **41** turns off transistor **42** thereby removing gate voltage from SCR **46**. SCR **46**, however, remains conductive until the anode to cathode current is reduced below the holding level. The combination of capacitor **48**, resistors **49**, **50** and **51** and the emitter-base junction of transistor **52** provides a current path through a second timing network designed to keep SCR **46**, and therefore transistor **52**, in the conductive state for a chosen time period, usually between five and ten seconds. While SCR **46** is on, transistor **52** is also on and supplies power to a decoupling network, comprised of resistor **53**, resistor **54** and capacitor **55**, and to oscillator circuit **33**. When SCR **46** is off transistor **52** is also off and no power is supplied to the decoupling network or oscillator circuit **33**.

The decoupling network prevents the oscillatory signal developed in oscillator **33** from affecting the timing intervals developed in timer circuit **32**. A substantially constant charge is developed across capacitor **55** during the on time of transistor **52** and in effect, provides the power supply for oscillator **33**.

The repetition rate of oscillator **33** is determined by timing resistor **56** and capacitor **57**. The pulse width is determined by feed back capacitor **57** and the inductance of the primary winding of transformer **59**. Upon application of supply voltage to oscillator **33**, transistor **58** turns on and due to charging of capacitor **57**, supplies a rapidly increasing current through the primary of transformer **59** until it becomes saturated and capacitor **57** is fully charged. At that time, the field collapses causing a polarity reversal which drives transistor **58** rapidly into cutoff where it is held until capacitor **57** discharges through a portion of the primary winding of transformer **59** and resistor **56**. Diode **60** protects transistor **58** during collapse of the field in transformer **59**. Oscillations continue in the manner described until transistor **52** turns off removing supply voltage from oscillator circuit **33**.

The changing field in the primary of transformer **59** induces a pulsing current in the two secondaries causing illumination of lamp **35** to indicate proper operation of the oscillator and supplying power to the output circuit. Resistors **61** and **62** provides I_{CBO} protection for transistor **63** and hold it in cutoff until a pulse appears on the secondary of transformer **59**. An induced pulse in the circuit containing resistors **61** and **62** and transistor **63** causes turn-on of transistor **63** thereby providing needed power gain and supplying current through the primary of trnsformer **64**. The current flowing through the primary of transistor **64** induces a current in the secondary of transformer **64** which is applied to the patient through electrodes connected to terminals **14** and **27**. A constant current output is achieved from this circuit. Diode **65** protects transistor **63** during field collapse in transformer **64**.

One pattern of electrical stimulation which has been effective to institute peristaltic activity without being noticable to the patient consists of passing ten volts into one thousand ohms to cause ten milliamperes of current to flow for a period of 0.100 millisecond once every twenty-five milliseconds. After five seconds, these pulses are terminated and no current flows for fifty-five seconds. Then the ten milliampere flow per 0.100 millisecond once every twenty-five milliseconds resume for another five seconds. The cycle is repeated every minute until positive results are obtained. The first such result may be observed by ausculatating the abdomen for bowel sounds. Positive results in the form of passage of feces or flatus will generally be observed from four to sixteen hours after stimulation has begun, and the stimulation may be discontinued following the first bowel movement.

Other patterns of electrical stimulation have proved effective where the rates of the application of stimulation approximated the normal periodicity of the inherent peristaltic pacemaker activity of the duodenum of the animal on which the apparatus was being used. In fact, stimulation in time cycles of the same general order of magnitude as the entire normal range of periodicity of the inherent peristaltic pacemaker action of the duodenum have been found effective.

Initially, experiments upon dogs' gastrointestinal motility were conducted to find optimal current amplitudes, pulse length frequency, and to determine feasible sites in the gastrointestinal tract for effective stimulation. Extensive experiments followed with various types of current in regard to wave shapes, pulse length and frequency and with regard to their effectiveness in inducing peristaltic activity. These findings were then tested and modified for human use based on experiments carried out on the researchers under fluoroscopy and later in the operating room by direct observation upon patients undergoing laparotomy.

It was found from these studies that a current of 7 to 10 milliamperes output and a frequency of 50 cycles per second given for 5–10 seconds duration and repeated in intervals of from 1 to 5 minutes would be sufficient to induce effective peristaltic activity. Such stimulation was found not to be perceptible to the patient.

The foregoing experiments are published in a paper entitled, "Gastrointestinal Pacing—a New Concept in the Treatment of Ileus," in the "Annals of Surgery," volume 158, No. 3, of September 1963, publisher J. B. Lippincott Company, U.S.A.

Since the foregoing studies were made, it has been found that up to 30 milliamperes of current can be used with a frequency of from 40 to 50 cycles per second and with this stimulation applied continuously for a first finite time period of from 5 to 10 seconds. The stimulation is then removed and repeated every minute.

With the use of the present invention, nasogastric suction may not be required following ordinary abdominal procedures. In these cases, fluid intake (drip feeding) may be administered through the catheter **10**, while the bowel activity is being restored and maintained by gastrointestinal stimulation or pacemaking in accordance with the invention.

Should nasogastric suction be indicated, this can be employed using the catheter **10** while the stimulation of the gastrointestinal tract is taking place as described. This suction will relieve excessive abdominal extension and will thereby shorten the patient's recovery time.

What is claimed is:

1. A method of treatment of paralytic ileus in the bodies of animals including humans including the steps of positioning a first electrode in the antral region in proximity to the pylorus in such a body, positioning a second electrode in spaced relation to the first electrode and in contact with said body, generating a series of electrical pulses and impressing said series of impulses between said electrodes for a first finite time period, allowing a second finite time period to elapse without any electrical impulses being impressed, and repeating the impulse and non-impulse steps until positive signs of restored peristaltic activity are observed; wherein said first time period is approximately five seconds and said first and second time periods together are approximately one minute.

2. A method of treatment of paralytic ileus in the bodies of animals including humans including the steps

of positioning a first electrode in the antral region in proximity to the pylorus in such a body, positioning a second electrode in spaced relation to the first electrode and in contact with said body, providing a generator of electrical impulses, electrically associating said electrodes with said generator, impressing a series of electrical impulses upon said generator across said electrodes for a first portion of a finite time period, allowing a second remaining portion of said finite time period to elapse without any electrical impulses being impressed, and repeating said impulse and no impulse steps during successive similar finite time periods until positive signs of restored peristaltic activity are observed, wherein said finite time period is approximately one minute.

3. The method of claim 2 wherein the step of positioning the first eletcrode includes positioning said electrode outside of one open end portion of a hollow flexible insulating tube and introducing said electrode and tube into the stomach through the nose and at least in part through the alimintary tract; wherein the step of electrically associating said first electrode with said generator includes extending a flexible electrical conductor from said generator, through said hollow tube and into electrical contact with said electrode; and the further steps of connecting said tube to a source of suction and performing nasogastric suction with said hollow open-ended tube during the repetition of said impulse and no impulse steps.

4. A method of treatment of paralytic ileus in the bodies of animals including humans including the steps of positioning a first electrode in the antral region in proximity to the pylorus in such a body, positioning a second electrode in spaced relation to the first electrode and in contact with said body, providing a generator of electrical impulses, electrically associating said electrodes and said generator, impressing a series of electrical impulses from said generator across said electrodes for a first portion of a finite time period, allowing no electrical impulses across said electrodes during a second remaining portion of said finite time period, and repeating said impulse and no impulse steps during successive similar finite time periods until positive signs of restored peristaltic activity are observed, said finite time period being approximately one minute and said first portion of said period being at least five seconds.

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