United States Patent [19]

Cami

[11] **3,885,561**

[45] **May 27, 1975**

[54] **CATHETER**

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[22] Filed: **Aug. 12, 1974**

[21] Appl. No.: **496,690**

Related U.S. Application Data

[63] Continuation-in-part of Ser. No. 312,236, Dec. 4, 1972, abandoned.

[52] **U.S. Cl.**..... **128/214;** 128/2 R; 128/348 R; 128/350 V

[51] **Int. Cl.**.. **A61m 5/00;** A61b 25/00; A61b 27/00

[58] **Field of Search**..... 128/214, 2 R, 2 B, 130, 128/224, 348, 349 R, 349 B, 349 BV, 350 R, 350 V

[56] **References Cited**

UNITED STATES PATENTS

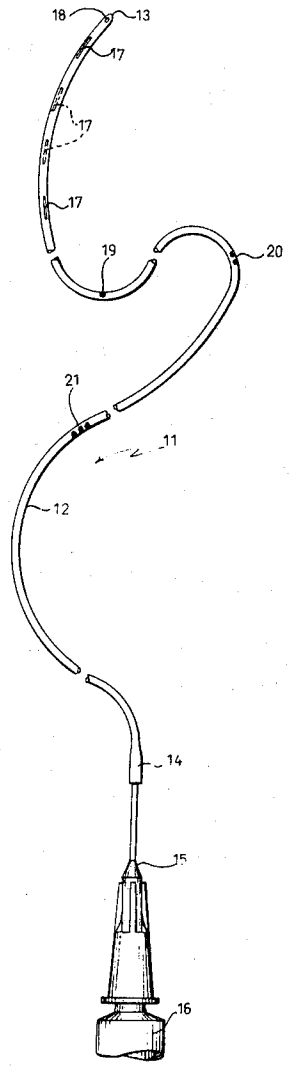
2,969,066	1/1961	Holter et al	128/350 V
3,020,913	2/1962	Heyer	128/350 V
3,086,525	4/1963	Whitcomb	128/232
3,483,859	12/1969	Pittman	128/2 R
3,485,234	12/1969	Stevens	128/348 X
3,599,641	8/1971	Sheridan	128/348
3,838,681	10/1974	Dalton	128/2 R

Primary Examiner—Aldrich F. Medbery
Attorney, Agent, or Firm—Ladas, Parry, Von Gehr, Goldsmith & Deschamps

[57] **ABSTRACT**

A catheter for epidural anesthesia comprising a plastic tube which has its near end open permitting adaptation to the tip of syringe or the like, and the opposite or distal end rounded and carrying embedded in the interior of same a metallic piece opaque to X-rays; having in the distal end, which is closed, from two to six longitudinal slits, each of which is both longitudinally and circumferentially offset from the nearest adjacent slit so that the diametral planes in which said slits are placed form a dihedral angle of at least 45°, and furthermore by the fact that none of the diametral planes in which each slit is located has more than one slit, thus affording the catheter practically the same rigidity as that of a catheter having no slit whatever.

3 Claims, 3 Drawing Figures



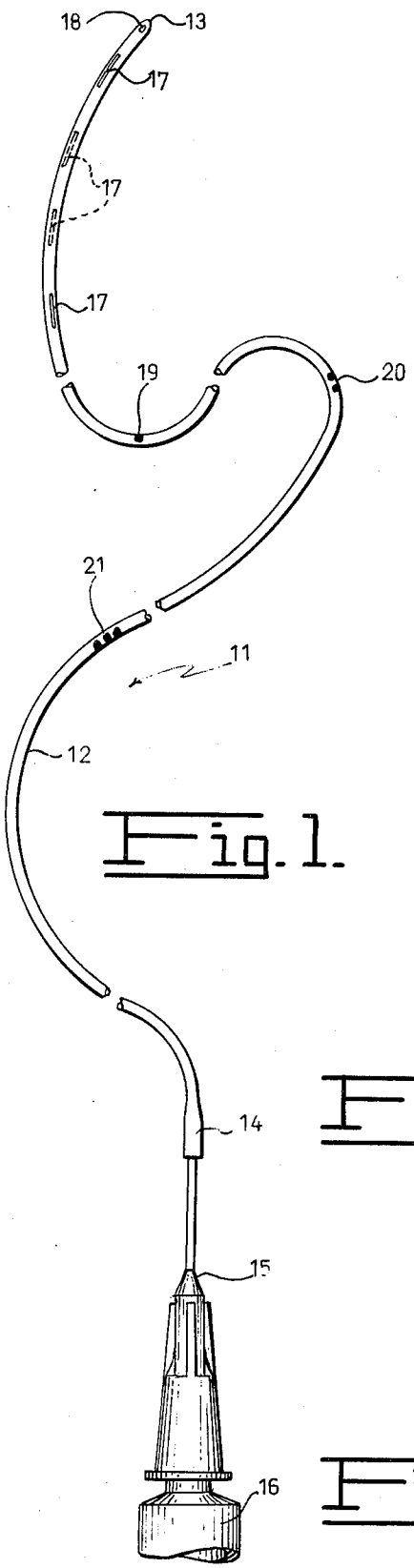


Fig. 1.

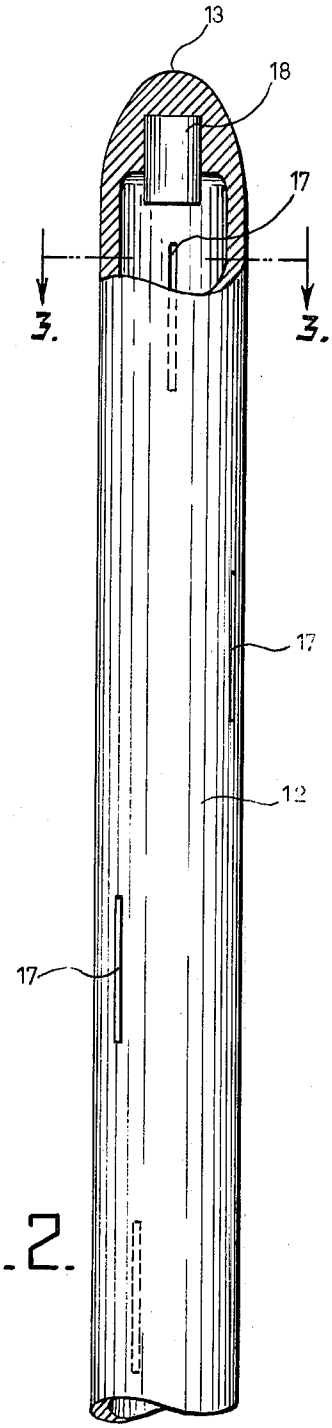


Fig. 2.

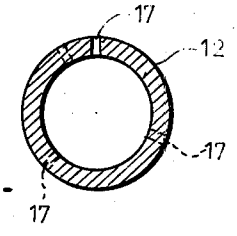


Fig. 3.

CATHETER

CROSS REFERENCE TO RELATED APPLICATIONS

This application is a continuation-in part of my copending application Ser. No. 312,236, filed Dec. 4, 1972, and now abandoned, for "Catheter."

BACKGROUND OF THE INVENTION

In recent years the technique of administering anesthetics in liquid form directly into the spinal column, specifically into the peridural space, has been improved, achieving benefits in comparison to general anesthesia of the patient, and particularly to that accomplished be means of anesthetic gases, in cases of surgery particularly of the lower abdomen and the legs, because the sensibility of the patient is successfully isolated in these areas without loss of consciousness, and without saturating the blood stream with anesthetic solutions.

Epidural anesthesia has also proved advantageous in childbirth, whether or not controlled by the introduction of ocitosics.

To administer this anesthesia it was at first necessary to insert a special needle into the resistant external tissues, between the vertebrae and through the softer and extremely delicate internal tissues before achieving penetration into the epidural space.

At first the anesthetic was administered directly through the needle, with the corresponding danger which a sharp pointed instrument of this character represents in such a critical spot.

Later on it became preferable to effect the operation by means of introducing a flexible tube of thermoplastic material of a diameter which could be passed through the inside of the needle which had been inserted into the body by direct puncture or by incision, permitting thereafter the extraction of the needle sliding over the tube when the latter had been placed in the desired location; this is tested by extracting through the tube a biological liquid sample. The tube of the first catheter had both ends cut square, and on one end it included a small adapter so that once the needle was withdrawn, a syringe with anesthetic could be attached.

Notwithstanding the advantages of the flexible catheter with square cut ends, over the administration of anesthetics by a simple needle, the edges of the square cut of the tube produce trauma in the delicate tissues through which the catheter passes and cause postoperatory pain to the patient; in addition, since the said catheter has no penetration markings, it is difficult to know to what depth the tube had been inserted.

Furthermore, with this tube the exact location of same in the epidural space is unknown, since the thermoplastic material of which it is made cannot be detected with X-rays.

Another problem caused by this catheter with square cut ends is that the orifice in the end of the tube frequently becomes blocked, since it is precisely the end, thereof that is used to achieve penetration, and hence in the opening of the tube tiny clots, fibers and particles of the tissue itself are deposited, obstructing the passage of the anesthetic liquid.

Subsequently, in order to avoid the foregoing problems, a catheter was developed which had the penetration tip at its distal end rounded to a bullet shape to reduce the trauma of adjacent tissues and to facilitate penetration through them.

The orifices for supplying the anesthetic in said catheter consisted of two practically circular lateral apertures near the distal end, diametrically opposite each other, and slightly separated from each other in respect to the lengthwise axis of the catheter.

Furthermore, in this catheter or probe indelible markings were provided separated by a certain interval, with the object of determining the penetration of the catheter.

Notwithstanding the progress achieved with this catheter, the shape and location of the lateral orifices seriously affected the strength of the tube, and weakened it, since the catheter in its penetration travel generally bends principally at the said orifices, causing serious complications such as the obstruction of the flow of the anesthetic liquid, difficulty in the withdrawal of the catheter when the bend is very pronounced, and occasionally the tip of the catheter comes off; obviously it is more difficult to accomplish penetration of the catheter under such conditions.

In addition to the problems mentioned with each of the catheters individually cited, they all uniformly have the drawback that, since within the epidural space there is a higher pressure than atmospheric pressure, the cephalorachidian liquid tends to escape through the catheter in cases where accidentally or intentionally the syringe is disconnected from the adapter or the latter from the catheter, thus producing a loss of the cited liquid with corresponding serious results.

In some catheters, in order to determine their position within the human body, heavy metals have been mixed with the plastic material; while this does produce a certain opacity which can be detected by X-rays, it is not very precise, since the epidural space into which the catheter is to penetrate is surrounded by bone tissue.

The above references are the best known in the field of catheters for epidural anesthesia; however, outside of this field, and for the sole purpose of differentiating them from the present invention, drain tubes or shunts operating on differential pressure may be mentioned; they are placed in the body permanently or for prolonged periods; some of them are for draining cerebrospinal fluid to either the atrium or the peritoneum. Since the pressure in the atrium is greater than the pressure in the cerebroventricular space, the drain tube has been provided with valving cuts at one of its ends, so as to prevent the back-flow of blood toward the ventricle; at its other end the drain tube has circular perforations; some of these tubes have as a backing member an inner concentric cylindrical body near the cuts to prevent the latter from becoming blocked; the arrangement of the cuts has not been made in these shunts specifically to give the tube strength, and furthermore, one of their ends generally carries circular perforations. Obviously, both the structural elements of these pressure shunts and their application are outside of the field of catheters for supplying epidural anesthesia of the present invention.

SUMMARY OF THE INVENTION

In view of the foregoing it is one object of the present invention to provide a catheter for epidural anesthesia which has its distal end rounded to prevent damage to the adjacent tissues during its penetration, thereof, and

which has embedded in the material of this distal end a piece of wire which is inert to biological tissue, which does not effect an ion interchange with biological fluids or tissue, and which may be stainless steel, with a low content of carbon, gold, platinum, alloys of cobalt, chrome and molybdenum, etc., and which is clearly detectable by X-rays even when the catheter is surrounded by bone tissue; and having penetration interval markings which will allow the user to determine the exact location of its application.

Another object of this invention is to provide a catheter having near its distal end a plurality of longitudinal radial slits to dispense the anesthetic which open only when a syringe or the like attached to the near end of the catheter develops a greater positive pressure than that prevailing in the cavity in which the anesthetic is to be delivered, or otherwise, when the syringe exerts a negative pressure or suction such that the slits open permitting the withdrawal of a sample of the biological liquid in order to determine the location of the catheter.

Each one of said radial slits is both longitudinally and circunferentially offset from the nearest slit so that no single diametral plane has more than one slit and the dihedral angle between diametral planes carrying adjacent slits is at least 45°, whereby the catheter is given the same rigidity as if it had no slits, enabling it to make easy penetration without the problems aforementioned due to bending of same.

These and other objects to be obtained through the use of this invention will be better understood and more fully perceived in the following description which refers to the attached drawings of the preferred embodiment of the invention.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1, is an elevational view showing the catheter of the present invention cut into sections and attached to an adapter at its near end, which is in turn coupled to the tip of a hypodermic syringe.

FIG. 2, is a detail view of the distal end of the catheter of the present invention, showing the longitudinal slits to deliver anesthetic, disposed in different diametral planes and in a conventional section showing the piece of metallic wire embedded in the inside of the distal end, which is easily detectable with X-rays.

FIG. 3, is a cross-sectional view along 3—3 of FIG. 2.

DETAILED DESCRIPTION OF THE INVENTION

The improved catheter **11** of the present invention, is composed of a tube **12** of thermoplastic material having a rounded distal end **13**, bullet shaped to facilitate its penetration through adjacent tissues until it reaches the epidural space, and having its near end **14** so made as to permit the attachement of an adapter **15** which in turn can be attached to a hypodermic syringe **16** partially shown, by means of which a positive pressure is applied to the anesthetic contained therein, causing it to pass through the length of tube **12** and discharging it in the epidural space through certain longitudinal slits **17** placed radially in relation to the longitudinal axis of tube **12** and so disposed in diametral planes that the dihedral angle formed between the diametral planes of two adjacent slits is at least 45° and that furthermore, none of the said diametral planes contains more than a single slit **17**, thus giving the catheter the same rigidity as if it had no slit whatever, to permit its ready penetration without the danger of bending or breaking.

The catheter **11** of the present invention further has embedded in the distal end **13**, thereof as shown in FIG. **2** a piece of metallic wire **18** which is inert to biological tissues and which does not engage in ion exchange with the biological liquids and tissues, being of such a material as stainless steel with low content of carbon, platinum, gold, alloys of cobalt, chrome and molybdenum, etc., said metallic portion **18** being readily detectable by means of X-rays even when catheter **11** is surrounded by bone tissue, as is usual in cases of epidural anesthesia.

The tube **12** also includes markings **19, 20, 21,** which are different from one onother and spaced along the catheter to show the person applying the anesthesia the location and penetration of the catheter and of the slits for delivering anesthetic. This indication can be further made more precise by means of X-rays, thereby detecting the position of metallic portion **18.**

Once the slots **17** for delivering anesthetic are in the intended epidural space a negative pressure is applied with the syringe **16** withdrawing a sample of the biological liquid and when the source of the latter has been determined a positive pressure is applied upon the anesthetic, delivering it through slits **17** into the epidural space.

The initial penetration of the catheter **11** is carried out as described at the beginning by passing it slidingly through a hypodermic needle, which is done by marking a prior incision or puncture in the external tissues of the patient, and later withdrawing this placement needle once the catheter **11** has been situated in the desired location.

It is important to note that the opening of slits **17,** is effected solely by the application of a positive or negative pressure, thus preventing the back-flow of fluid through a mere pressure difference due to carelessness with the resulting complications and problems.

While, the foregoing description has been drawn to a specific embodiment of the invention, it will be understood by all those skilled in the subject matter that changes in form and detail are encompassed withing the scope and spirit of the invention.

I claim:

1. A catheter for epidural anesthesia composed of a plastic material having its near end open and adapted for connection to a syringe and having its distal end closed and rounded and having embedded in its internal portion a metallic piece which is opaque to X-rays, said catheter having near its distal end a plurality of longitudinal slits for delivering anesthetic, each of said slits being both longitudinally and circunferentially offset from the nearest slit so that each slit be placed in a different diametral plane, and being so spaced from the adjacent slit that the diametral planes on which they are located form an angle of at least 45°, thus giving the catheter substantially equal rigidity to that of a catheter having no slit whatever.

2. The catheter for epidural anesthesia as described in claim **1,** wherein the slits for delivering anestesic consist of from two to six slits longitudinally spaced from each other.

3. The catheter for epidural anesthesia as described in claim **1,** wherein the metallic portion for detection by X-rays embedded within the distal end of the catheter is a piece of cylindrical wire which is inert to biological tissues and does not engage in ion exchange with the biological liquids and tissues.

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UNITED STATES PATENT OFFICE

CERTIFICATE OF CORRECTION

Patent No. 3,885,561 **Dated** May 27, 1975

Inventor(s) Charles N. MAZAL-CAMI

It is certified that error appears in the above-identified patent and that said Letters Patent are hereby corrected as shown below:

On the cover sheet, left column, the inventor's last name "Mazal Cami" should read-- Mazal-Cami--.

On the cover sheet, left column, below "[21] Appl. No.: 496,690" should be added

-- [30] Foreign Application Priority Data
December 15, 1971 Mexico.....132,127--.

Signed and Sealed this

twenty-third Day of *September 1975*

[SEAL]

Attest:

RUTH C. MASON
Attesting Officer

C. MARSHALL DANN
Commissioner of Patents and Trademarks