A method and a needle and catheter system for draining localized fluid collections, comprising: preloading a curved, pigtail catheter (22) by inserting through it a hollow cannula (10), the end (20) of the cannula (10) being formed with blunt and rounded edges (12). Next, a pointed stylet (14) is inserted through the hollow cannula (10). The stylet (14) is longer than the cannula (10) so that its end (18) will extend beyond the end (20) of the cannula (10) when received therethrough. The pigtail catheter (22) is made of a resilient material designed with a normal pigtail configuration and contains side holes (24) on the inner aspect of the distal pigtail (26). The next step involves inserting the two part needle (14, 10) having the catheter (22) mounted thereon into the desired tissue area (38), and then withdrawing the cannula (10) and stylet (14) while maintaining the drainage catheter (22) in the fluid location (42) such that the distal end (26) of the catheter (22) will return to its curved pigtail shape. Reformation of the pigtail catheter (22) to the curved shape at its distal end (26) assures positioning of its holes (24) within the fluid (42) for the final drainage step.
Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

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CATHETER-NEEDLE ASSEMBLY AND METHOD FOR DRAINAGE OF FLUID COLLECTIONS

Technical Field
The present invention relates to the drainage of fluid collections in the body, and more particularly to the percutaneous nonoperative techniques for drainage of localized fluid collections.
Recent widespread acceptance and performance of percutaneous drainage procedures, particularly by radiologists, has stimulated interest in safe, rapid, and more efficient ways of achieving percutaneous drainage. Present methods are only particularly effective and require an element of angiographic expertise, particularly with guidewire manipulation and catheter exchanges. Although most commonly performed under ultrasound or computed tomography alone, it is preferable to perform the manipulations under direct fluoroscopic vision.

The most widely accepted percutaneous approach to drainage of abscesses, cysts, and other localized fluid collections, with many individual variations of technique, involves initial puncture with a teflon sheath needle, introduction of a guidewire into the fluid, removal of the needle, dilation of the tract, and introduction of the drainage catheter. In one such approach known as the "Seldinger Procedure", a needle is introduced into the blood vessel, and guidewire is passed through the needle, the needle removed and the remaining guidewire used as a tract for a pigtail catheter prior to the drainage procedure. The guidewire must be removed before drainage can be performed. The guidewire is a tightly wound helix and adds substantial surface area to the blood which could result in blood clotting. Also, when using a pigtail over a guidewire, the thin, flexible guidewire will not completely straighten out the catheter. Furthermore, this procedure involves several time-consuming steps.
In view of the above-described disadvantages associated with the prior art drainage procedures, it is an object of the present invention to provide a technique, and an assembly therefor, for draining localized fluid collections in the body in a simplified procedure. It is another object to provide a needle-catheter system for drainage of fluid collections which is both simple and can be carried out with minimal instruction. It is another object to provide a technique for drainage of fluid collections which requires no specific expertise in catheter and guidewire manipulations.
Disclosure Of Invention

These and other objects are achieved by the present invention which provides a method for draining localized fluid collections, comprising: preloading a curved, pigtail catheter by inserting through it a hollow cannula having a blunt and rounded tip, inserting through the hollow cannula a pointed stylet with its point extending through the end of the cannula and the catheter, and inserting the two-part cannula and stylet having the catheter mounted thereon into the desired tissue area. The next step involves withdrawing the cannula and stylet while maintaining the drainage catheter in the fluid location such that the distal end of the catheter will return to its curved pigtail shape, and thereafter draining fluid from the area.

The present invention also provides a needle-catheter system for drainage of body fluid collections which includes a needle assembly and a pigtail catheter. The needle assembly includes a cannula which is hollow and has a blunt, rounded tip, and a pointed stylet adapted to be inserted through the hollow cannula. The pointed stylet is longer than the cannula so that the pointed end will extend beyond the end of the cannula when received therethrough. A pigtail catheter made of a resilient material, such as a polyethylene tubing, contains sideholes on the inner aspect of the distal pigtail, or curved end portion. The pigtail catheter is tapered distally to fit snugly around the cannula when mounted thereon to provide advancement through the body tissue with minimal resistance. The blunt and rounded tip of the cannula enables loading of the pigtail catheter on the cannula without cutting the catheter tubing, while the pointed stylet provides the puncture. The pigtail catheter has a resilient memory so as to change from its normal curved configuration to a straight configuration when the cannula is inserted therethrough, and thereafter return to its curved configuration as the pigtail catheter advances off the cannula. Reformation of the pigtail catheter to
its curved shape at its distal end assures positioning of its holes within the fluid being drained. In contrast, a straight catheter tip could protrude beyond the boundaries of the fluid-containing area, perforating adjacent tissue and causing significant trauma.
Brief Description of the Drawings

Figures 1A, 1B and 1C show the needle assembly comprising, respectively, the cannula, a close-up of the cannula tip and the pointed stylet;

Figure 2 shows the pigtail catheter to be employed with the needle assembly for drainage of fluid connections in accordance with the needle of the presentation;

Figure 3A shows the step of loading the pigtail catheter on the cannula;

Figure 3B shows the pointed stylet and cannula loaded in the pigtail catheter for making a percutaneous puncture; and

Figures 4A, 4B, 4C, 4D and 4E show the step-by-step technique of employing the catheter-needle assembly for draining a fluid collection.
Best Mode For Carrying Out The Invention

Referring to Figures 1A, 1B and 1C, there is shown the needle assembly comprising, respectively, in such figures a hollow, cannula 10, the end 20 of cannula 10 being formed with blunt and rounded edges 12, as shown in the exploded view of figure 1B, and a pointed stylet 14 having a sharp tip 18, such as a trocar point. The pointed stylet 14 is made of stainless steel and is slightly longer than the cannula 10 so that its tip 18 protrudes from the end 20 of cannula 10 when placed in the cannula for the purposes of the present invention. The two components, the cannula 10 and the pointed stylet 14 constitute a stainless steel needle.

In applicant's United States patent application serial No. 291,460 filed on August 10, 1981, there is disclosed a method and apparatus for draining localized fluid collections which employs a three-part needle assembly and a pigtail catheter. The three-part needle assembly includes a hollow cannula, a blunt obturator and a pointed stylet. The blunt obturator is used to load, on the cannula, the pigtail catheter which is made of a resilient material, such as polyethylene tubing. In some cases, the hollow cannula is manufactured with a tapered down, or feathered edge at the tip portion which might cause the scraping or cutting of the pigtail catheter tubing during the process of preloading the catheter by passing the cannula through the catheter to extend it from its normal curved configuration to a straight configuration.
Therefore, in such United States application, there is described the use of the inner blunt obturator having a blunt tip which extends beyond the cannula tip when inserted therethrough and thereby prevents the cannula tip from scraping or cutting the pigtail catheter during the preloading process. The above-described use of the blunt obturator, and the step associated with employing the blunt obturator and cannula combination for preloading the pigtail catheter, can be eliminated by designing the cannula 10 with its tip 20 having the blunt, rounded edges.
12 as shown in Figure 1B. In this fashion, the rounded edges 12 of cannula 10 ensure that the tip 20 will not scrape or cut the pigtail catheter tubing during the pre-loading step.

Referring to Figure 2, there is shown a pigtail catheter 22 of French size tubing 5, 7, 8.5 or 10 made of polyethylene or its copolymers which are generally between 6 and 9 inches in length. Size selection, of course, is determined by the size of the abscess and the type of fluid to be drained. Catheter 22 is modified to contain sideholes 24 on the area of the inner aspect of the distal pigtail 26. Catheter 22 is tapered on both its internal and external surfaces at the end 28 of the pigtail 26 so that it fits snugly on the cannula 10 which is inserted therethrough. This tight fit allows for advancements of the catheter-needle assembly through the body tissues with minimal resistance. In design of the system, the outside diameter of cannula 10 is approximately equal to the inner diameter of the distal tip of cannula 22 thereby assuring a tight fit therebetween. As described above, the catheter 22 may comprise a polyethylene or any other suitable material having a resilient memory. Also, cannula 20 is provided with a hollow hub 30 at its end portion and, similarly, stylet 14 is provided with a hub 34 at its end portion. Catheter 22 is provided with a hollow hub 36 which may have a knurled portion on its surface. Hub 30 is adapted for connecting a syringe for aspiration to remove fluid to verify position within the fluid collection. Hub 30 has an axial opening which will receive a portion of hub 34 when the stylet 14 is inserted in cannula 10, as shown in Figure 3B. Hubs 30 and 34 may be made of a chrome- or nickel-plated brass, while 36 may be made of a rigid, plastic material. Hub 36 is adapted for connecting a syringe for the substantially complete aspiration of the fluid in the abscess.

Figure 3A illustrates how the catheter 22 is loaded on the cannula 10 by advancing such cannula so that it gradually straightens the curve formed at the pigtail...
end 26, until the cannula 10 projects from the tip 28 of catheter 22. As shown in Figure 3B, once the cannula 10 projects through the tip of the catheter 22 to thereby straighten the same, the pointed stylet 14 is inserted such that the pointed tip 18 projects from the catheter 22 and the assembly is ready for the puncture operation. These steps of the procedure involving the mounting of the catheter 22 should be performed immediately prior to the fluid-draining procedure in order to maximize the reformation of the pigtail end 26. Otherwise, if the pigtail 26 is constrained to a straight configuration for prolonged periods of time, the polyethylene material has a tendency to lose its ability to reform to the pigtail configuration.

The fluid-draining catheter employing the pigtail distal end with holes on the inside of the loop has great practicality in its ability and simple operation in draining cysts, abscesses or wounds. The tubing, for example, may comprise a pigtail having a 1.5 cm radius with holes 24 drilled or punched with a 17 gauge cannula on the inside of the loop. As indicated in the drawings, the pointed stylet 14 used in a given assembly is slightly longer than the cannula 10, and both the cannula 10 and stylet 14 forming the needle are longer than the catheter 10 so that they protrude from the tip thereof.

Generally, fluid collections are localized with ultrasound or computerized tomography and the site of puncture, path and depth determined. The step-by-step technique of the present invention employing the catheter-needle assembly is illustrated in Figures 4A, 4B, 4C, 4D and 4E. Following skin preparation and local anesthesia, a small skin incision is made such as with a number 11 blade, in the body tissue 38 at point 40. The following steps (a) through (e) of the subject technique are illustrated by the Figures 4A through 4E corresponding thereto.

(a) The assembly, comprising the form shown in Figure 3B where it is ready for puncture, is advanced
through the body tissue 38 to the area where its end contacts the fluid collection 42 as shown in Figure 4A.

(b) The pointed stylet 14 is removed by grasping its handle 34, and aspiration on the needle cannula 10 is performed by a suction means 44 placed in line with the hollow end of the cannula handle 30 to confirm the position in the fluid collection, as shown in Figure 4B. In this connection, it is noted that this procedure for confirming the position of the catheter in the fluid collection cannot be performed by the conventional methods which require a guidewire since the guidewire does not allow for aspiration of the fluid.

(c) Once fluid is aspirated, the catheter-needle assembly is held firmly by the fingers 46 at the hub or handle 30 and the catheter 22 advanced, at the skin surface, off the cannula 10 as shown by the arrows 48 to a point into the fluid 42. This is shown in Figure 4C.

(d) As the catheter 22 advances off the cannula 10, as shown in Figure 4D, the pigtail 26 is immediately reformed and insures positioning of the holes 24 within the fluid collection 42. Because of the pigtail shape, it is extremely unlikely that further advancement of the catheter 22 will perforate the cavity at 42, but will instead cause further coiling within such cavity. Any excess resistance to advancement indicates improper catheter position and requires reevaluation.

(e) The cavity 42 can be aspirated completely, as shown in Figure 4E, as the holes 24 on the inner aspect of the pigtail will not become occluded by the surrounding tissue. A conventional hose 50 and suction device 52 or syringe is employed for this purpose. After complete aspiration, catheter 22 can either be removed or sutured at the skin site for continuous drainage by gravity or suction drainage, depending on the clinical need.

The present invention offers the following advantages:

(a) The entire drainage can be performed in a
simplified procedure. No extra
manipulations are required;
(b) No specific expertise is required in catheter
and guidewire manipulations as has
been required in the past;
(c) No fluoroscopy is necessary, and
(d) Position of the assembly is easily con-
firmed by aspiration of the fluid.

While the invention has been described above
with respect to its preferred embodiments, it should be
understood that other forms and embodiments may be made
without departing from the spirit and scope of the invention. For example, as described above in connection with
applicant's United States patent application serial No.
291,460, the hollow cannula can be employed with an inner
blunt obturator, not shown, in the form of a two-part needle which is used to preload the curved pigtail catheter.
The inner blunt obturator extends beyond the end of the
hollow cannula and its blunt tip enables loading of the
pigtail catheter on the cannula without cutting the catheter
tubing. In this example, the inner blunt obturator is
removed from the cannula after preloading and replaced
with the pointed stylet for the subsequent puncture proce-
dure. Thus, in this example, the inner blunt obturator is
used with the hollow cannula as a two-part needle during
preloading of the pigtail catheter, after which the inner
blunt obturator is removed from the cannula. The
remaining procedure involving puncturing the body tissue
with the needle having the catheter mounted thereon and
withdrawing the stylet and cannula for the drainage proce-
dure is identical to that described above.

What is claimed is:

SUBSTITUTE SHEET
-12-

Claims

1. Method for draining localized fluid collection in the body, comprising:
   preloading a pigtail catheter, having a curved pigtail end with a resilient memory for a distal end curve, by inserting therethrough a hollow cannula to change said pigtail catheter from its normal curved configuration to a straight configuration;
   inserting through said hollow cannula a pointed stylet which is adapted so that the pointed end of said stylet extends beyond the end of said cannula;
   inserting the two-part needle having the catheter mounted thereon into the desired area by puncturing the body tissue and advancing said needle to the area of said fluid collection; and
   withdrawing said stylet and cannula while maintaining said drainage catheter in the fluid location such that the distal end of the catheter will return to its curved pigtail shape, and thereafter draining fluid from the area through openings in said pigtail end.

2. Method as recited in claim 1 wherein said step of preloading said pigtail catheter is performed immediately prior to the step of puncturing the body tissue so that the ability of said pigtail catheter to reform to its pigtail configuration is maximized.

3. Method as recited in claim 1 wherein said pigtail catheter is comprised of a material having a resilient memory so that it will return to its curved pigtail configuration when said cannula is withdrawn from said catheter.

4. Method as recited in claim 3 wherein said pigtail catheter is made of polyethylene.

5. Method as recited in claim 1 wherein, subsequent to inserting said two-part needle into the desired area, withdrawing said pointed stylet from said cannula and aspirating through said cannula by a suction means to confirm the position of said catheter in said fluid collection.
6. Method as recited in claim 5 wherein, subsequent to said step of aspirating through said cannula to confirm its position, advancing said catheter off said cannula such that the pigtails end of said catheter is reformed within said fluid collection.

7. Method as recited in claim 1, further comprising providing sideholes on the inner aspect of said curved pigtails end to constitute said openings for draining fluid.

8. Method as recited in claim 1 wherein the end portion of said pigtails catheter is tapered distally to fit snugly on said cannula to permit advancement of said catheter through the tissues with minimal resistance.

9. A needle-catheter system for drainage of fluid collections, comprising:
   (a) a needle assembly including a hollow cannula and a pointed stylet for inserting through said cannula, said pointed stylet being longer than said cannula so that its end extends beyond the end of said cannula when received therethrough; and
   (b) a pigtails catheter made of a resilient material containing opening means on the curved distal pigtails for fluid drainage, the end portion of said pigtails catheter being tapered distally for advancement through the tissues with minimal resistance, said hollow cannula being used to load said pigtails catheter on said cannula, and said pointed stylet providing a puncture means, said pigtails catheter having a resilient memory so as to extend from its normal curved pigtails configuration to a straight configuration when it is loaded on said cannula and thereafter return to its curved pigtails configuration upon removal of said drainage cannula;
   whereby reformation of said pigtails catheter to its curved shape at its distal end will assure positioning of its drainage opening means within the fluid being drained.

10. System as recited in claim 9, wherein said pigtails catheter is comprised of a material having a
resilient memory so that it will return to its curved pigtail configuration when said cannula is withdrawn from said catheter.

11. System as recited in claim 10, wherein said pigtail catheter is made of polyethylene.

12. System as recited in claim 9, wherein said drainage opening means comprises a plurality of sideholes on the inner aspect of said curved pigtail end for draining fluid.

13. System as recited in claim 9, wherein said hollow cannula has a blunt tip which is rounded in its edges to prevent the cannula from cutting said resilient material of said pigtail catheter.
FIG. 1A

FIG. 1B

FIG. 1C

FIG. 2

FIG. 3A

FIG. 3B

SUBSTITUTE SHEET
# INTERNATIONAL SEARCH REPORT

**International Application No:** PCT/US82/01065

## I. CLASSIFICATION OF SUBJECT MATTER

According to International Patent Classification (IPC) or/and to both National Classification and IPC:


IPC: B61B 17/34, A61M 25/00

## II. FIELDS SEARCHED

**Minimum Documentation Searched:**

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Documentation Searched other than Minimum Documentation to the extent that such Documents are included in the Fields Searched.

## III. DOCUMENTS CONSIDERED TO BE RELEVANT

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<td>Y</td>
<td>US, A, 3,565,074 Published 23 February 1971 Foti</td>
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<td>N, Cordis Ducor R and the Angiographic System, Cordis Corporation, 1973 p.18</td>
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  - "Z" document member of the same patent family

## IV. CERTIFICATION

- **Date of the Actual Completion of the International Search:** 04 October 1982
- **Date of Mailing of this International Search Report:** 01 DEC 1982

**International Searching Authority:** ISA/US

**Signature of Authorized Officer:**

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Form PCT/ISA/D20 (second sheet) (October 1982)