Aug. 22, 1967 R. F. EDLICH 3,336,916

ELECTROCAUTERY PROCESS

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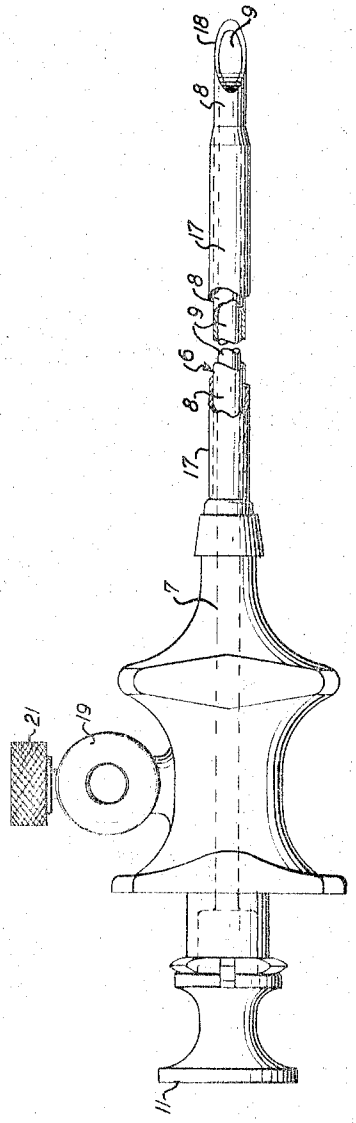


Fig. 1

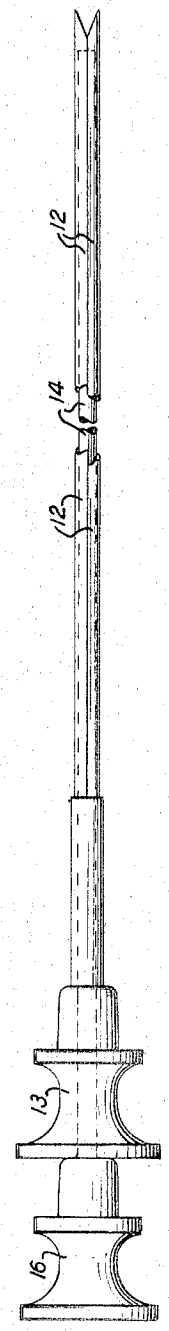


Fig. 2

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ELECTROCAUTERY PROCESS

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This invention relates to new and useful improvements in a method of reducing hemorrhage during the insertion or withdrawal of material through a cannula forced along an unnatural route into the interior of a live body and more particularly seeks to provide cannulas for removal of biopsy samples from or injection of material into various soft tissue organs such as the liver, spleen, brains, kidney, bile duct, etc.

Conventionally, biopsies are taken by (1) open surgery with all the attendant disadvantages of time consumption, surgical risk and added expense or (2) cannula needle insertion which is quicker, simpler and cheaper but is frequently complicated by hemorrhage which leads sometimes to death. Liver biopsies are probably the most common performed by cannula and the bleeding tendency and impaired coagulation associated with liver disease undoubtedly enhance the danger of severe bleeding. In patients with composed hepatocellular damage, deficiencies in proconvertin (Factor VII), proaccelerin (Factor V) and plasma thromboplastin are severe enough to result in abnormal bleeding.

Unfortunately, the standard methods used to detect coagulation disorders are not always reliable indicators of the bleeding potential at a particular site. One-stage prothrombin-times, e.g., often cannot detect a defect in hemostasis in the chronic liver disease patient. Various investigators have shown a correlation between the incidence of hemorrhage and the type of liver disease so that a liver biopsy should not be performed with certain diseases.

A further complication in percutaneous biopsies relates to the size of the cannula used. The needle aperture and usable length is in an almost direct relation to the amount of tissue withdrawn to be analyzed. However, the larger the cannula size, the greater the amount of bleeding. Thus, in severe cases of liver disease, it is necessary to reduce the needle size which results in less specimen to examine.

Various methods to prevent hemorrhage in liver biopsies have been (1) avoidance of the procedure in patients with metastatic carcinoma and jaundice, (2) use of an external biopsy needle combined with peritoneoscopy where electrocautery can be used to stop the bleeding (elaborate and painful) and (3) the local application of hemostatic agents into the puncture wound at the completion of the liver biopsy (prolongs the duration of the intrahepatic manipulation).

Therefore, it is an object of this invention to reduce the time and severity of bleeding caused by the withdrawal of cannulas.

It is also an object of this invention to permit use of larger cannulas for percutaneous procedures without running a risk of hemorrhage.

It is a further object of this invention to permit percutaneous cannula procedures under a greater variety of conditions.

I have found that bleeding caused by withdrawal of cannulas may be greatly reduced by covering the cannula, except for the distal end, with a thin non-conducting sheath and applying an electrocautery coagulation current to the proximal end of the cannula during withdrawal.

With the above object and features in view, the nature of which will be more apparent, the invention will be more fully understood by reference to the drawings, the accompanying detailed description and the appended claims.

In the drawings:

FIG. 1 is a perspective partially broken view of a Franklyn type, Silverman outer needle (cannula) and fitted stylet modified in accordance with this invention; and

FIG. 2 is a perspective partially broken view of the inner split needle and assembly stylet which need not be modified.

This invention as illustrated is applied to a Franklyn modified Silverman needle although obviously applicable to most any type of cannula used to transport material to or from a subcutaneous site.

As shown in FIG. 1, the outer needle **6** comprises the needle hub **7** and cannula **8** with a fitted inner stylet **9** having a handle **11** thereon. FIG. 2 shows the inner split needle **12** with its handle **13**, an assembly stylet **14** therein and its handle **16**. All of the elements described to here will be recognized as conventional.

Surrounding the cannula **8** is a fixed thin sheath **17** of Teflon (Du Pont trademark for polytetrafluoroethylene) extending from the hub **7** to within 2 mm. of where the bevel **18** begins. Any insulating material could be used that is compatible with insertion into the body such as rubber, various inert plastics, silicones, but Teflon has been found very desirable because of its extreme inertness, ease of sterilization, non-wettability and workability.

Secured to the needle hub **7** is a connecting terminal **19** having a threaded knob **21**. This terminal is adapted to be connected by wire to an electrocautery unit so that the needle **6** becomes the operative electrode on activation of the current with the distal cannula end extending preferably from 1–10 mm. beyond the Teflon sheath **17** being the working tip of the electrode.

The conventional use of this Silverman needle is fairly obvious. The outer needle **6** with the fitted stylet **9** in place is introduced into the liver by puncturing the abdominal wall to the appropriate depth but considerably short of touching the skin with hub **7**. The fitted stylet is removed and replaced with the inner split needle **12** and assembly stylet **14** with the latter being removed. The inner split needle **12** is then passed through and beyond the cannula **8** to grasp the liver biopsy specimen. The outer needle **6** is then advanced to finish severance of and secure the specimen.

At this point, the entire unit is normally withdrawn and the risk of hemorrhage is relatively high. However, the terminal **21** is connected to an electrocautery unit (not shown), the switch turned to coagulation current and the unit withdrawn whereby the cannula serves as an electrode and seals the potential bleeding spots along the entire path made by the outer needle. Any electrocauterizer having coagulation current (Bovie Model CSV or Cameron 255, e.g.) may be used and will be found in any hospital in the operating room. However, since the present procedure is not surgical and will be conducted in a hospital bed or the physician's office, it is preferred to use a smaller portable electrocauterizer rather than the large fixed units which are always in the operating room and suggest major surgery to the patient.

The current input for coagulation is quite variable and generally is a spark gap arrangement with damped oscillation currrent. The wattage may be from 20 to 120, preferably 30 to 75, depending to a great extent upon the resistance offered by a given patient and the type of procedure being followed. Obviously the needle must be metal or other electro-conductive material and the uncovered tip not too large to dissipate large amounts of current.

The efficacy of the above described needle and method has been tested on dogs and humans. In experiment one, five dogs with systolic pressures of 100–140 (mm. Hg) were each biopsied under visual observation with and

without electrocautery in two different lobes. After bleeding had stopped, systolic hypertension was produced by the administration of metaraminol (m-hydroxynorsephedrine) and biopsies performed as before in different lobes.

In experiment two, elevated prothrombin times were produced from 18 to 128 seconds in five dogs by the administration of Warfarin [believed to be the popular designation of the Wisconsin Alumni Research Foundation for 3-(α-acetonylbenzyl)-4-hydroxycoumarin].

In experiment three, five dogs were prepared by ligation of the common bile duct.

Test	Treatment	Cautery	Bleeding Time Average (secs.)
I	Control	No	117
I	do	Yes	46
I	Hypertensive	No	253
I	do	Yes	128
II	Elevated prothrombin	No	(1)
II	do	Yes	(2)
III	Duct ligation	No	225
III	do	Yes	151

[1] Always uncontrolled bleeding.
[2] Only one uncontrolled bleeding.

Histological sections were made of all biopsy sites and no significant differences were noted except for a small area of coagulation necrosis surrounding each electrocautery biopsy site. Although the biopsy specimen was never removed prior to electrocautery, surprisingly there was no evidence of coagulation necrosis of any biopsy sample.

Appropriate statistical analysis will demonstrate the statistical significance of the above reductions in bleeding times.

In addition, the inventor has used the needle and process described herein on ten human subjects for liver biopsies without any evidence of bleeding, i.e. no changes in blood pressure, pulse, hemoglobin, hematocrit or bilirubin.

The invention has been specifically described in reference to liver biopsies with a Franklyn-type Silverman needle but is obviously applicable to any percutaneous procedure where a material is to be transported through a cannula to or from a site beneath the skin. Thus for liver biopsies, the same technique could be applied to the Menghini aspiration needle or others and in fact is applicable to any biopsy taken through a cannula. Furthermore, if hemorrhage is a problem on introducing material through a cannula, the same technique can be applied, e.g. radiopaque dyes in transhepatic cholangiograms and splenoportograms. In other words, the invention is applicable to the reduction or elimination of bleeding caused by the use of percutaneous cannulas.

Needle has been used herein as synonymous with cannula or hollow needle (as it is so used in medicine) as the invention by its very nature (transport of material) is limited to a hollow needle or cannula.

Although this invention has been described with a certain degree of particularity, it is understood that the present disclosure of the preferred form has been made by way of example and that numerous varieties of uses for different parts of the body and subsequent changes in the details of construction may be resorted to without departing from the spirit and the scope of the invention.

I claim:

1. In a process for transporting material through the skin and underlying tissue with a percutaneous electrically conductive cannula-needle that forms its own path with a sharpened end, the improvement in combination therewith comprising operably connecting said cannula-needle to an electrocautery circuit and cauterizing said path as said cannula-needle is withdrawn by passing a cauterizing current to said sharpened end from the opposed end of said cannula-needle while electrically insulating the remainder of said cannula-needle from contact with the skin and underlying tissue.

2. The process of claim 1 in which said current is a coagulating current.

3. The process of claim 2 in which said material is a biopsy sample.

4. The process of claim 2 in which said material is a radiopaque dye.

5. In a process for performing a biopsy through the skin and underlying tissue, the steps of introducing into living flesh an electrode percutaneous cannula-needle having a cannula portion electrically insulated from living flesh except at its sharpened end, obtaining the desired tissue sample for biopsy, and electrically connecting said cannula-needle to an electrocautery circuit while simultaneously withdrawing said cannula-needle whereby to cause the uninsulated sharpened end of said cannula portion to cauterize the tissue along the path of withdrawal.

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