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[54] **FINE NEEDLE ASPIRATION BIOPSY OF PROSTATE**
2 Claims, 3 Drawing Figs.

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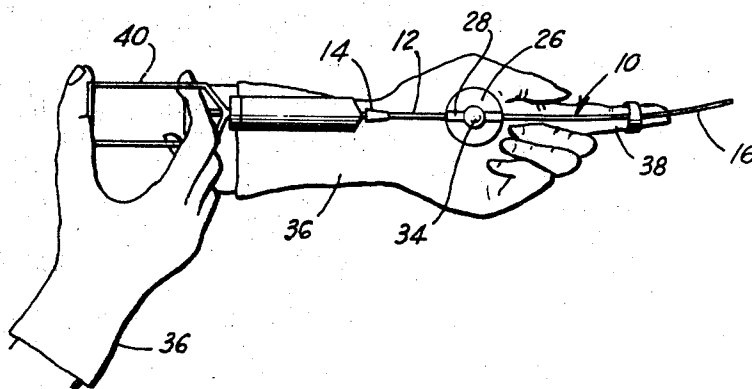
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ABSTRACT: A method and means for biopsy of the prostate gland utilizing cytologic studies as a basic for presumptive diagnosis. A biopsy needle is passed through a guide which may be fixed to the operator's gloved finger by a ring member. After the guide is placed on the finger, a finger cot is applied over the apparatus and finger for sterility and to facilitate insertion of the guide and finger internally of the body. The needle is then inserted through the guide and into the substance of the prostate. A syringe is attached to the needle and utilized for withdrawing a tissue sample whereupon slides are prepared for diagnosis of prostatic malignancy.



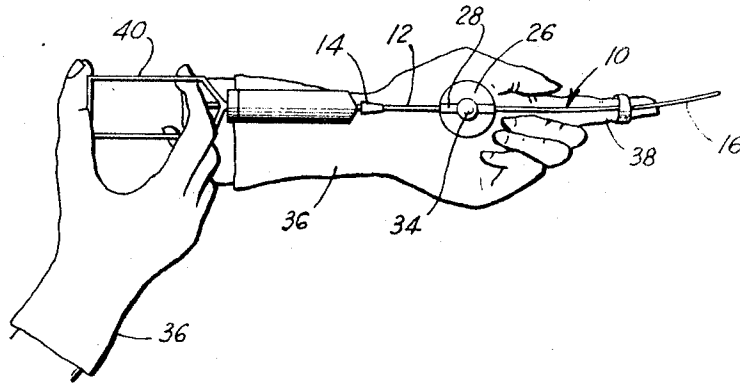


Fig. 1

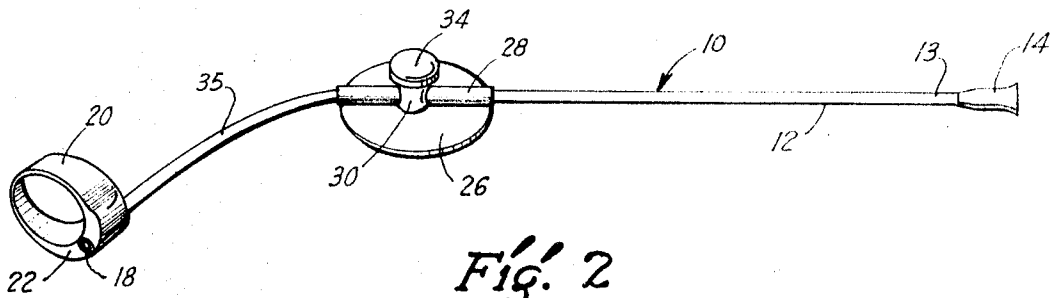


Fig. 2

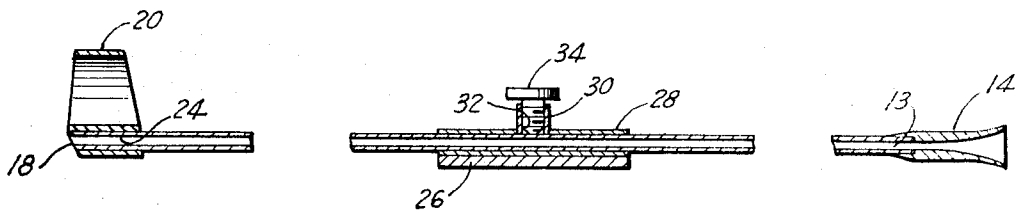


Fig. 3

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FINE NEEDLE ASPIRATION BIOPSY OF PROSTATE

This invention relates to improvements in biopsy methods and means and more particularly, but not by way of limitation, to a method and means for biopsy of the prostate gland utilizing cytologic studies for presumptive diagnosis.

A method of biopsy of the prostate gland utilizing cytologic studies as a basis for presumptive diagnosis was first developed and introduced in Sweden and has been of great advantage in the detection of prostatic malignancy, or the like. However, certain disadvantages are present in the method in that the equipment used is often of a size causing discomfort to the patient.

The present invention contemplates an improvement in the technique of this type of biopsy which is considered to be a step forward in earlier diagnosis of prostatic malignancy. A guide device has been particularly designed and constructed for disposition on the gloved finger of the operator by means of a ring. The usual finger cot may then be applied over the finger and apparatus for sterility and to facilitate insertion of the finger and guide into the rectum of the patient. The biopsy needle is then inserted through the guide and transrectally into the substance of the prostate. A syringe is attached to the needle and suction is produced by pulling on the plunger of the syringe. A to-and-fro or in-and-out movement of the syringe and needle is produced while exerting suction, whereby movement is effected to disturb the prostate tissue sufficiently so prostatic cells and fluid are aspirated into the needle. The suction is then released and the needle is removed or withdrawn from the tissue. Cellular debris remains in the lumen of the needle, and the needle is then removed from the guide. Several slides are then prepared for the analysis of the cellular debris. The quantity of the debris and the method of preparing the slides provides excellent nuclear detail, thus enabling classification of the cells according to Papanicolaou's criteria. The outstanding results possible by study of the slide prepared in accordance with the invention appears to be the visualization of the nucleoli. The pleomorphism of the nucleoli and increase in number of the macronucleoli can easily be seen, thus providing an earlier diagnosis of prostatic malignancy.

It is an important object of this invention to provide an improved method and means for biopsy of prostate utilizing cytologic studies as a basis for presumptive diagnosis.

It is another object of this invention to provide a guide for a biopsy needle which greatly facilitates the insertion of the needle into the rectum of the patient and into the substance of the prostate.

Another object of this invention is to provide a novel guide and biopsy needle and method particularly designed and developed for improving the removal of cellular material from the prostate for biopsy purposes.

Still another object of this invention is to provide a method of preparing slides from the cellular material removed from the prostate for improved diagnosis of prostatic malignancy.

A further object of this invention is to provide an improved method and means for biopsy of prostate wherein visualization of the nucleoli is greatly increased.

Other and further objects and advantageous features of the present invention will hereinafter more fully appear in connection with a detailed description of the drawings in which:

FIG. 1 is a side elevational view of a fine needle aspiration biopsy device embodying the invention and disposed in the hands of an operator.

FIG. 2 is a perspective view of a guide device embodying the invention.

FIG. 3 is a broken sectional elevational view of the guide device shown in FIG. 2.

Referring to the drawings in detail, reference character 10 generally indicates a needle guide comprising an elongated tube 12 having one end 13 thereof open and a flared sleeve member 14 secured thereto for facilitating insertion of a biopsy needle 16 therein. The opposite end 18 of the tube 12 is also open whereby the needle 16 may pass completely

through the tube for a purpose as will be hereinafter set forth. A ring or annular member 20 is secured to the end 18 of the tube 12 in any suitable manner. As shown herein, the ring 20 is provided with an enlarged circumferential portion 22 having a longitudinal bore 24 extending therethrough for receiving the end 18 therein. The end 18 may be soldered or otherwise rigidly secured within the bore 24 for securing the ring 20 to the tube 12.

A disc member 26 is provided with a diametrically extending sleeve 28 secured to one face thereof for slidably receiving the tube 12 therethrough. An outwardly extending sleeve 30 is suitably secured to a bore 32 provided in the sleeve 28 and is internally threaded for receiving a thumbscrew or setscrew 34 therein. The disc 26 may be positioned at substantially any desired position on the tube 12 for stabilization thereof during use and may be securely retained in the selected position by threading the screw 34 in the sleeve 30 until the screw 34 bears against the outer periphery of the tube 12. The tube 12 is preferably provided with an arcuate portion 35 in the proximity of the end 18 whereby the overall configuration of the tube 12 is generally complementary to the configuration of the internal portions of the body wherein the device is to be inserted, as will be hereinafter set forth. Of course, the disc 26 may be positioned on the tube 12 as desired for facilitating the holding of handling of the device 10 as will be hereinafter set forth.

In use, the operator or user of the invention initially puts on the usual sterile gloves 36 and the guide 10 may be fixed to the operator's gloved index finger 38 by the ring 20. The usual finger cot (not shown) is then applied to the finger 38 over the guide device 10 to maintain sterility and to facilitate insertion of the finger into the rectum of the patient (not shown). The patient is preferably draped in the normal lithotomy position (not shown) and no special preparation technique in the office of the operator is required. Only the preparations normally utilized for cystoscopic examinations on hospitalized patients in the surgery suite are required. As a practical matter it has been found that a prior injection of any suitable mild analgesic agent is sufficient to prevent undue discomfort to the patient when performing the diagnostic method of the invention in the office of the operator.

With the apparatus or guide 10 in position on the finger 38 the disc 26 may be positioned along the tube 12 as desired for facilitating handling of the guide 10 and maintaining a stability for the tube 12. For example, as shown in FIG. 1, it may be preferable to position the disc 26 in the proximity of the palm of the hand, or it may be desirable to position the disc 26 in the proximity of the base of the finger 38. In any event, the flared sleeve or open end 14 of the tube 12 will be exposed in the proximity of the palm of the hand for receiving the biopsy needle 16 therein.

When the guide 10 is properly disposed on the hand of the operator, the index finger 38 is inserted into the rectum of the patient and the prostate (and/or nodule, if present) is palpated, as is well known. The configuration of the guide 10 substantially conforms to the internal structure of the body in this area for facilitating the insertion of the guide 10 and finger 38. The needle 16 is then inserted into the flared sleeve 14 and through the tube 12 and transrectally into the substance of the prostate or nodule. Whereas the needle 16 may be of any suitable type, it has been found preferable to use a 9/16 inch 22 g. needle, with the needle being of either the long-bevel type or short-bevel type. The long-bevel type needle is particularly useful in performing routine biopsy, and the short-bevel type needle is particularly useful in aspirating a discreet nodule or suspicious area. In performing a routine biopsy, it is preferable to make two sets of slides (not shown) as will be hereinafter set forth, and use two needles in order that both lateral lobes may be examined.

When the needle 16 has been inserted into the substance of the prostate, a suitable syringe 40 is secured or attached to the outer end of the needle 16 in the usual manner. The syringe 40 may be of any suitable type. However, a 20 cubic centimeter

syringe has been found to be very satisfactory. A to-and-fro (or insand-out) movement of the syringe 40 and needle 16 produced simultaneously with the exertion of suction by the syringe. The purpose of this movement is to disturb the tissue of the prostate or nodule sufficiently so prostatic cells and fluid are aspirated into the needle 16. The suction or negative pressure applied by the plunger of the syringe is then released slowly prior to removal of the needle from the tissue. This will permit the cellular debris (not shown) to remain in the lumen (not shown) of the needle 16. The needle 16 is then removed from the tissue of the prostate or nodule and from the guide 10.

A plurality of slides (not shown) are prepared from the cellular material or debris. This is accomplished by expressing a drop of the bloody fluid (cellular debris) on each slide and very delicately smearing the fluid with the flat surface of a second slide, taking care not to spread the tissue elements off the end of the slide being made. The smear is then allowed to air-dry until the gloss or sheen has disappeared, and then the smear is fixed with several drops of 95 percent alcohol, and again allowed to air-dry. The slide is then ready for staining.

The present method has been successful in obtaining adequate tissue and cellular material for cytological examination. When the slide is stained with Giemsa and differentiated with Eosin, it has been found that excellent nuclear detail is obtained, enabling classification of the cells according to Papanicolaou's criteria. However, the outstanding feature of this staining method is the visualization of the nucleoli using this staining technique. The pleomorphism of the nucleoli and increase in number of the macronucleoli can easily be seen. As a result it is felt that a step toward earlier diagnosis of prostatic malignancy may be achieved. In addition, as a technique, the procedure is simple, fast relatively atraumatic and safe, and to date there have been no complications as a result of practicing the method or technique.

From the foregoing it will be apparent that the present invention provides a novel method and means for biopsy of the prostate gland utilizing cytologic studies as a basis for presumptive diagnosis. A guide member is particularly designed and constructed for installation on the index finger and in the hand of the operator whereby the biopsy needle may be more easily and readily inserted transrectally into the substance of the prostate or nodule. A syringe utilized in conjunction with the needle facilitates the capture of cellular debris or tissue for examination purposes. Slides are prepared from the tissue or

cellular samples in a manner wherein excellent nuclear detail is obtained for facilitation classification of the cells according to Papanicolaou's criteria, and visualization of the nucleoli is greatly improved by the use of the staining technique. In addition, the device and technique are simple, quick and efficient in results.

Changes may be made in the combination and arrangement of parts as heretofore set forth in the specification and shown in the drawings, it being understood that any modification in the precise embodiment of the invention may be made within the scope of the following claims, without departing from the spirit of the invention.

What I claim is:

1. A guide for biopsy needle comprising needle receiving means, finger receiving means secured to the needle receiving means, and stabilizing means adjustably secured to the needle receiving means for facilitating handling thereof during a biopsy procedure, said stabilizing means comprising a disc member, a sleeve carried by the disc member for slidably receiving the needle receiving member therethrough, and means carried by the sleeve and engageable with the needle receiving means for selectively securing the disc to the needle receiving means.

2. A guide for a biopsy needle comprising needle receiving means, finger receiving means secured to the needle receiving means, and stabilizing means adjustably secured to the needle receiving means for facilitating handling thereof during a biopsy procedure, said needle means comprising an elongated tubular member having the opposite ends thereof open for slidably receiving the needle therethrough, one of said open ends being flared for facilitating insertion of the needle therein, said finger receiving means comprising an annular member adapted for receiving a finger therein, said tubular member being provided with an arcuate portion for facilitating guiding of the needle, said annular member being secured to the tubular member in the proximity of the opposite open end thereof, said stabilizing means comprising a disc member, a sleeve member carried by the disc member for slidably receiving the tubular member therethrough, setscrew means carried by the sleeve and engageable with the tubular member for selectively securing the disc member on the tubular member, and said tubular member being provided with an arcuate portion in the proximity of the annular member for facilitating handling of the guide and guiding the needle passing therethrough during a biopsy procedure.

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