Diagnosis

INNOVATION IN MEDICAL DIAGNOSIS—THE SCANDINAVIAN CURIOSITY

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Summary Fine-needle aspiration biopsy is a major diagnostic tool in Scandinavia, where 8000 such biopsies may be done in a large metropolitan hospital each year. The procedure is rapid, inexpensive, and technologically simple, yet it has found only limited, albeit increasing, acceptance in medical practice outside Scandinavia. Although the differences between Scandinavian and other medical systems may explain why the technique is not used more widely, there seems to be an underlying reluctance among medical communities to accept subjective types of innovation compared with objective innovation.

INTRODUCTION

INNOVATION in medicine is a curious process. Some new diagnostic or therapeutic procedures, such as surgical procedures and technological innovation (e.g., computerised tomographic scanning), are accepted immediately by the medical community and rapidly placed in service. Other, less objective, innovations may take decades and require persistent advocacy before final and general acceptance. A classic example of the latter group is exfoliative cytology for the diagnosis of cervical cancer, which has had a long and troubled history. First reported in 1928 independently by Papanicolaou and Babes, exfoliative cytology was not really accepted until almost a quarter century later, when it received the support of such agencies as the American Cancer Society.[1,2]

Another procedure undergoing this agonising process of being widely accepted is the use of fine-needle aspiration biopsy (FNAB) for the diagnosis of palpable tumours. First introduced in America in the 1930s by Martin and Ellis[3] and Stewart[4] (an early opponent of exfoliative cytology) and subsequently largely abandoned in America, the procedure was adopted in Sweden where, through the efforts of Franzén,[5] Zajicek,[6] Söderström,[7] and others, it has become a routine and extremely well-documented technique used in the diagnosis of palpable or localisable tumours.

FNAB IN SWEDEN

Although FNAB cytology may be applied to many organs, including liver, lung, and pancreas (with localisation by ultrasound or X-ray), for the purposes of discussion I will consider it with respect to only the breast, thyroid, and prostate. The methods of and cytological criteria for FNAB are well documented.[6,7] Briefly, the method consists of the palpation of the organ or mass, the insertion of a disposable hypodermic needle with a diameter of less than 0·8 mm, and the aspiration of cells that are spread on slides and stained, usually with a May-Grünwald-Giemsa or Papanicolaou stain or both. It is even possible to obtain enough material for œstrogen-receptor[8] or cytochemical[9,10] studies without serious inconvenience to the patient. The advantages of this procedure are both humanitarian and medical—about 95% of women with breast cancer can be diagnosed before surgery, and in elderly men with prostatic disease ten biopsies an hour can be done without anæsthesia or serious side-effects. In one moderately large hospital in Stockholm about 3000 breasts, 1500 thyroids, and 700 prostates are aspirated each year by a staff of three or four cytopathologists. Other hospitals in Scandinavia have similar loads.

The difference between the popularity of the procedure in Scandinavia and the apparent disinterest shown in the technique by other countries may rest in differences in the structure of medical practice rather than in difference in diagnostic skills.[11] The Swedish cytopathologist, for example, is employed by his hospital (although some "moonlight" in the few private practices left in Sweden). The cytopathologist is usually a certified pathologist with several years experience in cytopathology. Patients are referred to a centre specialising in cytopathology, where any woman, with or without breast lumps, may attend without being referred. The cytopathologist is provided with the patient's clinical details and X-rays, and the attending physician's comments. He then examines the patient, does the biopsy himself, carefully checks that the sample is adequate, and assesses how well the lesion is represented. Often an additional biopsy sample is taken (patients can usually tolerate several repeat aspirations). The slides and notes made are sent to a laboratory where the slides are stained. On the same, or the next, day the cytopathologist himself reads the slides and dictates his report and makes recommendations for any further diagnostic tests. In urgent cases, a cytological diagnosis of a suspicious lesion may be obtained within a half hour. Consultations are the general rule and many reports bear double signatures, usually of a senior and a junior cytopathologist. On average, a cytopathologist sees about 35 patients per day over about six hours; it takes about half a day to discuss and interpret these patients' slides.

Since FNAB is not only a faster, less painful, less expensive, and less technologically demanding technique for the diagnosis of neoplasia than those generally used in many countries, but also does not require the services of surgeons and anæsthetists and/or extensive capital investment, it would be ideally suited for use in underdeveloped countries.

WHY FNAB IS NOT POPULAR OUTSIDE SCANDINAVIA

Why has this technique, with all its advantages, not become more widely used? Some Scandinavian physicians believe that in other countries, especially those with fee-based systems, economic considerations such as surgical biopsy fees may have induced a reluctance to adopt a cheaper and simpler method. Non-Scandinavian physicians attribute their own disinterest to difficulties in obtaining properly trained personnel, fear of law suits (especially in the U.S.A.), or to fears that the technique represents "second class" methods of obtaining a histopathological diagnosis. These more or less ad hominum arguments are not really satisfactory. Although no one in Sweden would suggest that aspiration cytology could or should replace conventional histopathological diagnosis, there is general agreement that it is a very useful

addition to the more time-honoured techniques both for diagnosis and for following the course of treatment of patients with neoplastic diseases. It also reduces the numbers of frozen sections which, according to many histopathologists, is perhaps desirable.

"Medical" reasons for its unpopularity, such as tumour growth in the needle track, are both unfounded and derive from observations made with coring biopsy needles quite unlike those used in Scandinavia—for example, in one Swedish hospital alone, none of more than 18 000 thyroid biopsies done over the past twenty-five years have been known to result in needle-track spread of malignant disease. FNAB does give both false-negative and false-positive findings, but the incidence of these is low; besides, such findings are also well known with conventional histopathology[12] and exfoliative cytology.[13] Furthermore, the method seems as reliable as other supportive methods of diagnosis such as mammography.

To me, the difference seems to arise because, although ultimately all diagnoses are more or less subjective, the evidence on which they are based can be either objective or subjective. Objective evidence is usually gathered by machines that, because of their complexity, may also require development time before they become common. Objective methods, such as electrophoresis, gas-liquid chromatography, high-pressure liquid chromatography, and radioimmunoassay are incorporated into routine service at a rate proportional to cost and their acceptability to medical technology. Some "borderline" methods require longer trial periods—for example, electrocardiography.

Subjective findings, based entirely on interpretation by a skilled observer, require time for the observers to build up enough experience and then more time for them to gain the confidence of their fellow practitioners. Sometimes even extremely skilled observers have difficulty in explaining why they are convinced that a tissue has undergone a particular change or why a cell "looks" atypical, yet time or necropsy substantiates their belief.

The acceptance of FNAB in Scandinavia has been fairly rapid compared with that of exfoliative cytology. One reason for this could be that the set-up for early FNAB studies was the same as that for bone-marrow biopsies; this similarity made FNAB acceptable from the start since most physicians were used to having hæmatologists both examine the patient and prepare and read the smear. Another reason could be that histological biopsy specimens were also routinely obtained so that the cytopathologist had ready confirmation of his cytopathological findings.

The factor responsible for the long and agonising period before acceptance of methods of diagnosis such as stethoscopy, mammography, exfoliative cytology, and FNAB should be recognised by public-health planners, especially those who intend to start cancer-control programmes or fund development programmes. The factor is the subjectiveness of the interpretation of a new test; the more subjective the nature of the interpretation, the longer the time required for acceptance of the test. In most cases, this time is equal to one to two professional lifetimes, or about 20–40 years.

As to the future of FNAB, there have recently been attempts to make it an objective method through the application of computerised pattern recognition.[14] The results of such studies may speed acceptance in countries where FNAB by cytopathologists is not standard practice.

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